IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA *ex rel.* PETER HUESEMAN,	§	
	§	
	§	
Plaintiff,	§	**SA-14-CA-212-XR**
	§	
v.	§	
	§	
PROFESSIONAL COMPOUNDING CENTERS OF AMERICA, INC.,	§	
	§	
	§	
Defendant.	§	

THE UNITED STATES' RESPONSE TO DEFENDANT'S MOTION TO DISMISS THE COMPLAINT IN PARTIAL INTERVENTION

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INTRODUCTION

This case concerns rampant fraud against the United States. From 2012 to 2015, Professional Compounding Centers of America (PCCA) and its compound pharmacy customers enriched themselves at the expense of the TRICARE Program, which provides health care coverage for active-duty military personnel, retirees, and their dependents. The government brought this action under the False Claims Act (FCA) and common law against PCCA for its role in causing TRICARE to pay hundreds of millions of dollars for false and fraudulently inflated claims for compound prescription drugs. These compound drugs included creams, gels, and ointments containing chemical ingredients supplied by PCCA to its customers, who then billed TRICARE thousands of dollars for each compound claim based on PCCA's fraudulent pricing.

The government alleges that PCCA had complete control over both the pricing metric frequently used to determine TRICARE reimbursement for compound claims—known as the Average Wholesale Price (AWP), which PCCA reported for each ingredient—and the selling price of each ingredient. PCCA fraudulently inflated its AWPs—often by thousands of percent over its selling prices—to create large "spreads." PCCA marketed its inflated AWPs and large "spreads" to induce its customers to buy its ingredients. Those customers then submitted compound claims containing PCCA ingredients to TRICARE for payment based on PCCA's inflated AWPs, which caused TRICARE to pay hundreds of millions of dollars in excess reimbursements—until TRICARE stopped the fraud. To avoid liability, PCCA makes specious arguments that ignore the controlling legal standards, disregard the complaint's well-pleaded facts, and blame TRICARE for PCCA's own fraudulent conduct. The court should reject these arguments and deny the motion to dismiss.

SUMMARY OF THE ARGUMENT

The Fifth Circuit disfavors motions to dismiss and has made clear they should be "rarely granted." *See Harrington v. State Farm Fire & Cas. Co.*, 563 F.3d 141, 147 (5th Cir. 2009). This case is no exception. The government has more than plausibly alleged that PCCA violated the FCA by causing the submission of false claims, based on a fraudulent course of conduct and violations of the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b), and by making false statements material to false claims. Dkt. 66 ¶¶180–89. The complaint satisfies each element of the FCA: falsity, materiality, knowledge, and causation.

Interplay Between the FCA and AKS. Claims resulting from violations of the AKS are false and material under the FCA as a matter of law. PCCA violated the AKS by knowingly and willfully offering remuneration to its customers through fraudulently inflated AWPs, large profit spreads, and other benefits to induce sales of its ingredients, which TRICARE reimbursed. Dkt. 66 ¶¶52–111, 141–49. PCCA's argument (Dkt. 84 at 3) that the AKS does not apply because its ingredients were not "covered" by TRICARE is inconsistent with the text and purpose of the AKS, contrary to caselaw, and would lead to absurd results Congress never intended.

Falsity. Even though AKS violations establish falsity as a matter of law, the government adequately pleaded falsity for two additional reasons. First, PCCA reported false and fraudulent AWPs that were material to TRICARE's payment for compound claims. Dkt. 66 ¶186–87. Second, PCCA engaged in a fraudulent course of conduct that caused TRICARE to pay inflated amounts for compound claims with PCCA's ingredients. *Id.* ¶181. Numerous courts have rejected PCCA's argument (Dkt. 84 at 13) that, in the absence of a specific definition, AWPs cannot be false or fraudulent as a matter of law, no matter how divorced they are from actual prices.

This Court should reject PCCA's improper effort (Dkt. 84 at 14–15) to graft onto the FCA an "objective falsity" requirement—like an "express falsity" requirement the Supreme Court

rejected in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 579 U.S. 176 (2016). The Fifth Circuit recently rejected an "objective falsity" requirement in a criminal health care fraud case, and other circuits have declined to read an "objective falsity" requirement into the FCA. Nevertheless, under any objective measure, PCCA's AWPs were false and fraudulent.

Materiality. PCCA's AKS violations are material as a matter of law. The complaint also adequately pleads materiality under the FCA's statutory definition and *Escobar*'s holistic, multi-factor approach. *See* Dkt. 66 ¶¶152–78. PCCA argues the government cannot plead materiality because TRICARE continued to pay claims even though it knew AWPs were "list" or "sticker" prices and because TRICARE lacked authority to pay for bulk ingredients. *See* Dkt. 84 at 26. But PCCA ignores facts alleged in the complaint—specifically, that TRICARE implemented controls that stopped payment on almost all compound claims with inflated AWPs. PCCA's contentions about TRICARE's authority to pay for ingredients and about its pharmacy benefits manager, Express Scripts, Inc. (ESI), have no bearing on the materiality analysis.

Knowledge. The complaint adequately pleads that PCCA acted with actual knowledge, deliberate ignorance, or reckless disregard as to the falsity of its AWPs. Dkt. 66 ¶¶181, 186. PCCA contends it did not act "knowingly" as a matter of law because it "could have held" the interpretation that TRICARE did not cover its ingredients. Dkt. 84 at 36. The allegations in the complaint, which must be taken as true, contradict PCCA's contention and plead facts showing that PCCA knew both that its customers billed TRICARE for its ingredients and that TRICARE reimbursed those customers based on PCCA's AWPs. Dkt. 66 ¶¶5, 55.

PCCA misreads *Safeco Insurance Co. of America v. Burr*, 551 U.S. 47 (2007), a case that addressed the Fair Credit Reporting Act, to disclaim FCA knowledge based on a post hoc interpretation it contends is objectively reasonable. The Supreme Court later clarified *Safeco* in

Halo Electronics, Inc. v. Pulse Electronics, Inc., 579 U.S. 93 (2016), and refused to allow a defendant to evade enhanced damages by asserting a post hoc interpretation. Regardless, PCCA's interpretations are objectively unreasonable and inconsistent with caselaw and guidance that should have warned PCCA away from its fraudulent conduct.

Causation. The complaint pleads causation because PCCA played a direct and substantial role in causing the submission of fraudulently inflated compound claims to TRICARE. Dkt. 66 ¶¶150–51. The submission of these claims to TRICARE was the direct, foreseeable, and natural consequence of PCCA's actions. *Id*. PCCA attempts to divert attention away from its actions by casting blame on TRICARE—the victim of its fraudulent scheme—and on other third parties, including its own customers. Dkt. 84 at 46. This attempt neither breaks the chain of causation nor insulates PCCA from the consequences of its actions.

Common Law Claims. Lastly, the government sufficiently pleads claims for payment by mistake, unjust enrichment, and common law fraud. *See* Dkt. 66 ¶¶190–201. PCCA contends the allegations are insufficient because it did not directly benefit from its misconduct, there is no contract between PCCA and TRICARE, and PCCA never made a misrepresentation directly to the government. *See* Dkt. 84 at 55–60. Neither the facts alleged in the complaint nor the law support these contentions. Accordingly, PCCA's motion to dismiss should be denied in its entirety.

FACTUAL BACKGROUND

Compounding Overview. PCCA sells chemical ingredients to compounding pharmacies. Dkt. 66 ¶1–2, 52. Its pharmacy customers use these ingredients to prepare and dispense compound medications for patients. *Id*. ¶52.[1] These pharmacies then submit claims for reimbursement on

[1] Compounding is a practice in which a licensed pharmacist combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Dkt. 66 ¶2 n.1.

behalf of covered patients to insurance programs such as TRICARE. *Id.* TRICARE reimburses compound claims based on the lesser of the following amounts: (1) the sum total of the AWPs (minus a contracted discount) for all ingredients in the compound drug, plus a dispensing fee and level of effort fee; (2) the sum total of costs submitted by the pharmacy for the compound drug, plus a dispensing fee and level of effort fee; or (3) the pharmacy's usual and customary charge for the medication. *Id.* ¶45. Under this methodology, TRICARE's reimbursement for compound claims submitted by PCCA customers was frequently based on PCCA's reported AWPs. *Id.* AWP is a standard pricing benchmark used by government health care programs and commercial insurance companies in determining reimbursement amounts for drug products. *See id.* ¶¶53–55. PCCA determined and reported AWPs for its chemical ingredients to commercial pricing compendia, which publish AWPs submitted by manufacturers and suppliers. *See id.* ¶¶2, 53–54.

PCCA's Fraudulent Course of Conduct. In March 2012, PCCA sharply increased the AWPs on its ingredients—more than doubling them in some instances. *Id.* ¶72 (identifying ten PCCA ingredients and the increase in their AWPs). PCCA's AWPs bore no rational relationship to PCCA's selling prices and generated enormous "spreads" between its customers' acquisition costs and their potential profit from reimbursement. *See id.* ¶¶60–61 (identifying ingredients with AWPs ranging from 1,323% to 56,461% of selling prices). PCCA used its high AWPs and large spreads as a marketing tool to drive sales of its ingredients, knowing that customers would bill TRICARE and other third-party payers based on the inflated AWPs. *Id.* ¶74. Because PCCA's selling prices for its ingredients were typically higher than its competitors, PCCA's senior management instructed sales personnel to compete not on selling price, but on AWP reimbursement. *Id.* ¶¶75–79. The complaint provides over twenty paragraphs of examples of

PCCA's sales representatives marketing its high AWPs and mega-spreads to induce customers to purchase its ingredients. *See id.* ¶¶87–111.

In addition, PCCA taught customers how to bill compound claims to insurance to get the "widest spread possible." *See id*. ¶¶112–16. It offered customers billing software with features that enabled them to automatically submit compound claims to ensure reimbursement based on AWP, rather than a lower "usual and customary" price. *Id*. ¶117. And PCCA raised certain already-inflated AWPs even further in response to customer requests. *Id.* ¶¶84–86.

PCCA also promoted lucrative compound formulas (i.e., specific combinations of ingredients in specific proportions) to demonstrate how much money its customers could make by purchasing PCCA ingredients and billing insurance, including TRICARE. *See id.* ¶¶80–82, 93, 98, 104, 108. One written update to senior management described customers as "salivating when we were showing the new . . . Formulas and Reimbursement." *See id.* ¶81. Many of those compound formulas involved pain, wound, and scar creams containing many ingredients with high AWPs and large spreads. *Id.* ¶80.

For example, PCCA heavily promoted fluticasone propionate and formulas containing that ingredient. *See id.* ¶¶127, 129–32. PCCA typically sold fluticasone propionate to its top customers for under $200 per gram, but reported an AWP in 2014 of $3,630.90 per gram, generating a spread of more than $3,400 for each gram of fluticasone propionate used in a compound claim. *Id.* ¶126. By 2015, fluticasone propionate became PCCA's top-selling ingredient. *Id.* ¶132. PCCA's markup for resveratrol was even more egregious. PCCA typically sold this ingredient to its customers for under $2 per gram, but it reported an AWP in 2014 of over $800 per gram, more than 400 times PCCA's selling price. *Id.* ¶¶6, 137–38.

PCCA's Knowledge of Its Fraudulent Actions. PCCA knew that its customers valued high AWPs and large spreads. *See id.* ¶¶7, 56–59, 74. PCCA viewed AWP as a proxy for an ingredient's reimbursement and used the term "AWP" and "reimbursement" interchangeably. *Id.* ¶56. PCCA knew that the higher the AWP, the greater the reimbursement to its customer, and that a larger spread usually meant a greater profit for the pharmacy. *Id.* ¶59. At the same time, PCCA recognized that artificially inflating AWPs to create large spreads for its customers was risky and would drive customers to purchase ingredients and submit compound claims because of the spread. *See id.* ¶¶65–68, 70. PCCA also knew inflating AWPs would likely trigger audits, scrutiny, and investigations. *Id.* Despite this knowledge, PCCA ignored the risks and decided to dramatically increase its already inflated AWPs to drive sales. *See id.* ¶¶69–72.

PCCA knew its AWPs were false and fictitious numbers, having no relationship to actual prices. *See, e.g.*, *id*. ¶¶67, 69–70, 72, 85–86, 155–57. PCCA also knew that at least one insurance auditor had disallowed certain compound claims after it learned of PCCA's selling prices and compared them to PCCA's AWPs. *Id.* ¶154. For these reasons, PCCA sought to conceal its selling prices from third-party auditors. *See id.* ¶¶153–57. In seminars it held, PCCA implored its customers never to disclose PCCA's selling prices to auditors: "Please, do not ever give them your costs." "You need to call us." "Do not give them your costs, ever." "It's going to create huge problems for you." "Don't let [auditors] see your acquisition costs. That is a disaster waiting to happen." *Id.* ¶156.

PCCA knew that inflated AWPs resulted in excessive reimbursement and abusive billing practices. *See, e.g.*, *id.* ¶¶1, 85, 113, 119–21, 128, 130. One PCCA executive lamented that inflated AWPs were causing many pharmacies to charge the system "$2500-$3000 per script that normally would sell for around $75.00." *See id.* ¶119. Another PCCA executive wrote to PCCA's

senior management about the exorbitant amounts pharmacies were billing to third-party payers, commenting, "[y]ou can shear a sheep many times but can skin him only once." *Id.* ¶120. As one compound pharmacist acknowledged to PCCA: "[a]s crappy as it is, pharmacies are using fluticasone [propionate] in formulas because of the super high AWP reimbursement. It's done for financial reasons, therapeutics be darned." *Id.* ¶130.

PCCA knew its customers billed TRICARE for compound claims containing its ingredients and knew TRICARE determined reimbursement based on its AWPs. *See id.* ¶¶5, 55, 59, 118, 159, 162. PCCA actively monitored TRICARE's compound reimbursement policies and communicated with PCCA customers about TRICARE's compound coverage. *See id.* ¶¶118, 159. PCCA also knew its profits were tied to TRICARE's continued payment of compound claims and hired a lobbyist to delay TRICARE changes to compound coverage. *See id.* ¶159. When its efforts initially succeeded, the lobbyist wrote to PCCA's President, "another delay equals another victory for PCCA and ALL of your member pharmacies." *Id.*

The Harm to TRICARE. PCCA directly benefitted from its fraudulent scheme and experienced almost a quadrupling of its ingredient sales over a three-year period. *Id.* ¶¶13, 158. PCCA's benefit came at the expense of TRICARE, which experienced an explosion in the number and cost of compound claims, especially in the first four months of 2015. *See id.* ¶¶14, 133, 139, 179. PCCA's fluticasone propionate and resveratrol were included in almost 28,000 compound claims submitted to TRICARE, accounting for over $200 million in TRICARE compound costs. *See id.* ¶¶123, 133, 139. The complaint identifies 325 compound claims containing these and other PCCA ingredients with inflated AWPs billed to TRICARE in amounts ranging from $2,000 to over $46,000 per claim. *See id.* ¶123.

TRICARE acted to curtail payment even as PCCA lobbied against changes to TRICARE's coverage and payment policies. *See id.* ¶¶159–61, 170–71. In November 2014, the Department of Defense (DOD) Pharmacy and Therapeutics (P&T) Committee unanimously recommended a prior authorization process for compound claims. *Id*. ¶160. Following input from TRICARE's Beneficiary Advisory Panel, TRICARE implemented enhanced electronic screening and prior authorization for compound claims, effective May 2015. *Id.* ¶161. Once TRICARE implemented these controls, the number of fraudulently inflated compound claims to TRICARE declined sharply. *See id.* So too did PCCA's sales. PCCA's annual revenue plummeted from over $244 million in 2014 to under $90 million in 2015. *Id.* ¶163. PCCA's President acknowledged, "Tricare changes in reimbursement took a huge toll on our members' purchases. Wowzer!" *Id.* ¶162.

PROCEDURAL HISTORY

In March 2014, the relator filed his complaint in this matter under the FCA's *qui tam* provisions, alleging that PCCA's fraudulent AWP scheme violated the FCA and AKS. Dkt. 1 ¶¶8, 199–210. After investigating the matter, the government filed its complaint in partial intervention in November 2021. Dkt. 66. The government alleged two FCA claims: (1) PCCA knowingly caused to be presented false or fraudulent claims to TRICARE; and (2) PCCA knowingly made, used, or caused to be made or used false records or statements that were material to false or fraudulent TRICARE claims. *Id.* ¶¶180–89. In addition, the government pleaded common law claims of payment by mistake, unjust enrichment, and fraud. *Id*. ¶¶190–201.

STANDARD OF REVIEW

In reviewing a Rule 12(b)(6) motion, the court must accept the complaint's allegations as true and view them in the light most favorable to the plaintiff. *United States v. Bollinger Shipyards, Inc.*, 775 F.3d 255, 261 (5th Cir. 2014). "The complaint must be liberally construed, with all reasonable inferences drawn in the light most favorable to the plaintiff." *Morgan v. Swanson*, 659

F.3d 359, 370 n.17 (5th Cir. 2011) (quoting *Woodard v. Andrus*, 419 F.3d 348, 351 (5th Cir. 2009)). To survive a Rule 12(b)(6) motion, the complaint need only contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is plausible if it "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The court should not "look behind [a complaint's] allegations and independently assess the likelihood that the plaintiff will be able to prove them at trial." *Bollinger*, 775 F.3d at 260 (quotations omitted). The allegations need only "be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Twombly*, 550 U.S. at 555. Plausibility is not "probability" and does not require detailed factual allegations. *Id.* at 556.

FCA claims must also comply with Rule 9(b)'s particularity requirements. *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 185 (5th Cir. 2009). The government must "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Rule 9(b) "only requires simple, concise, and direct allegations of the circumstances constituting fraud." *Grubbs*, 565 F.3d at 186 (quotations omitted). An FCA complaint is sufficient if it alleges "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id.* at 190. "Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b); *see also Bollinger*, 775 F.3d at 260 (no particularity required for knowledge).

ARGUMENT

I. The Government Adequately Pleaded Violations of the Anti-Kickback Statute.

The AKS imposes liability on any person who "knowingly and willfully offers or pays any remuneration . . . directly or indirectly, overtly or covertly, in cash or in kind to any person to

induce such person . . . to purchase . . . or arrange for or recommend purchasing . . . any . . . item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2)(B). The government pleads a violation of this section where it alleges that the defendant (1) knowingly and willfully offered remuneration to any person; (2) to induce such person; (3) to purchase or arrange for the purchase of any item; (4) for which payment may be made in whole or in part under a federal health care program. *See United States v. Medoc Health Servs. LLC*, 470 F. Supp. 3d 638, 648 (N.D. Tex. 2020).

"[I]f claims are submitted in violation of the AKS, they are considered false claims under the FCA as a matter of law." *United States ex rel. Wheeler v. Union Treatment Ctrs., LLC*, No. SA-13-CA-4-XR, 2019 WL 571349, at *5 (W.D. Tex. Feb. 12, 2019); *accord* 42 U.S.C. § 1320a-7b(g) (codifying proposition). AKS violations are also "inherently material" under the FCA "to the government's decision to pay claims presented." *United States v. Marlin Med. Solutions, LLC*, No. SA-21-CV-00160-OLG, 2022 WL 190308, at *8 (W.D. Tex. Jan. 12, 2022).

In 2003, HHS-OIG published guidance that addressed the AKS implications of AWP manipulation. *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23737 (May 5, 2003) (OIG Guidance). The OIG Guidance was part of an effort "to engage the health care community in preventing and reducing fraud and abuse in federal health care programs." *Id.* at 23731. The Guidance noted that in certain federal programs, "pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who . . . thereafter bill the federal health care programs will be reimbursed." *Id.* at 23736. The OIG Guidance explained, "[t]o the extent that a manufacturer controls the 'spread,' it controls [the] customer's profit." *Id.* Because various

"payers base reimbursement for drugs and biologicals on AWP," the OIG Guidance warned manufacturers not to manipulate AWPs to induce customers to purchase their products:

> If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. . . . [I]t is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product.

Id. at 23737; *see also* Dkt. 66 ¶37. The OIG Guidance specified, "[t]he conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute." 68 Fed. Reg. at 23737.

A. PCCA Knowingly and Willfully Offered Remuneration to Induce the Purchase of PCCA Ingredients Paid by TRICARE.

Courts and HHS-OIG have interpreted the term "remuneration" broadly to include "anything of value in any form whatsoever." *Marlin Med.*, 2022 WL 190308, at *6 (quotations omitted); *see also United States ex rel. Derrick v. Roche Diagnostics Corp.*, 318 F. Supp. 3d 1106, 1113 (N.D. Ill. 2018); Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35958 (July 29, 1991). PCCA's inflated AWPs and the resulting mega-spreads constitute remuneration because PCCA's customers valued high AWPs and profited from large AWP spreads through increased reimbursements from TRICARE. As explained in the OIG Guidance, "manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser." 68 Fed. Reg. at 23737. Here, PCCA's manipulation of its AWPs transferred remuneration to PCCA's customers from TRICARE.

The complaint alleges that PCCA knowingly and willfully[2] offered remuneration to its customers—in the form of egregiously inflated AWPs, corresponding profit spreads, and other benefits like all-expense paid vacations—to induce customers to purchase PCCA ingredients billed to TRICARE. Dkt. 66 ¶¶52–111, 141–49. The complaint provides over twenty paragraphs of examples in which PCCA's sales representatives marketed its high AWPs and mega-spreads to induce customers to purchase ingredients. *See id.* ¶¶87–111. In addition, the complaint provides extensive detail of PCCA's use of all expense paid "WOW" trips to destinations such as Cancun, Mexico for "Diamond" customers who made at least $300,000 in annual purchases from PCCA. *See id*. ¶¶141–49. PCCA used its "WOW" trips as a "negotiating tool" and an incentive to purchase more ingredients. *See id*. ¶¶146–49.

PCCA does not dispute that the complaint adequately alleges PCCA knowingly and willfully offered remuneration or that its offers of remuneration induced customer purchases. Instead, PCCA contends the government failed to tie that remuneration to specific claims for payment. Dkt. 84 at 54. The government does not need to tie specific offers of remuneration to particular claims to plead FCA claims premised on underlying AKS violations. *See Marlin Med.*, 2022 WL 190308, at *4 (government need only plead particular details of a scheme paired with reliable indicia leading to a strong inference that claims were actually submitted). Nevertheless, the government identified 325 specific claims submitted to, and paid by, TRICARE—each claim containing PCCA ingredients with inflated AWPs. *See* Dkt. 66 at Ex. 22. And the government

[2] The complaint alleges facts showing that PCCA acted "willfully" for purposes of the AKS. The AKS specifically provides that "a person need not have actual knowledge of this section or specific intent to commit a violation of this section." 42 U.S.C. § 1320a-7b(h). Instead, the government need only show that a defendant willfully committed an act that violated the AKS. *See United States v. St. Junius*, 739 F.3d 193, 210 (5th Cir. 2013). "That is to say, the defendant committed the act voluntarily and intentionally, and not necessarily with the purpose to violate the AKS." *Marlin Med.*, 2022 WL 190308, at *4.

alleged with detail PCCA's scheme, establishing a strong inference that "Diamond" members who were offered or attended WOW events submitted TRICARE claims, including a significant number of the claims identified in Exhibit 22. *See, e.g.*, *id.* ¶¶141–49, 163 (changes in TRICARE coverage led to sharp decline in purchases from Diamond customers).

B. The AKS Applies to PCCA's Conduct in This Case.

i. The "Payment May Be Made" Requirement Is Plainly Satisfied.

PCCA contends that any claims premised on AKS violations should be dismissed because it argues that "PCCA's products and compounded medications incorporating them were not covered by TRICARE." Dkt. 84 at 3. This argument is a red herring. This Court need not decide whether PCCA's products are "covered" because the AKS is not limited to kickback schemes for items that are "covered."[3] Whether an item or service is legally reimbursable by a federal health care program is not an element for stating a claim under the AKS. By its very language, the AKS applies when kickbacks are offered, paid, or received in connection with any item "for which *payment may be made* in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2)(B) (emphasis added). The "payment may be made" requirement is satisfied whenever a kickback scheme is connected to federal "program-related business." *See Marlin Med.*, 2022 WL 190308, at *3; *United States ex rel. Bruno v. Schaeffer*, 328 F. Supp. 3d 550, 560 (M.D. La. 2018) (requiring only a "nexus" between "Medicare or Medicaid business" and

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[3] PCCA points to TRICARE's regulations that exclude from its basic benefit "[u]nproven drugs, devices, and medical treatments or procedures." 32 C.F.R. § 199.4(g)(15). A drug is "unproven" if it "cannot be lawfully marketed without the approval or clearance of the [FDA] and approval . . . has not been given at the time the drug . . . is furnished to the patient." *Id.* § 199.4(g)(15)(i)(A). Although PCCA notes that its products are not FDA approved, it has not argued that its products (i.e., bulk ingredients) "cannot *be lawfully marketed* without the approval or clearance of the [FDA]." *Id.* (emphasis added). Were it to make such an argument, PCCA would essentially be conceding that its entire business selling bulk ingredients is unlawful.

kickbacks for private insurance patients); *United States v. Ctr. for Diagnostic Imaging, Inc.*, 787 F. Supp. 2d 1213, 1221 (W.D. Wa. 2011) ("[T]he AKS prohibits willfully offering remuneration to induce the referral of program-related business[.]" (emphasis omitted)).

The term "payment" refers to "the act of paying." *See* https://www.merriam-webster.com/dictionary/payment (last visited May 22, 2022). Use of the word "may" denotes possibility. *See* Black's Law Dictionary (11th ed. 2019) (defining may as "to be a possibility"); *United States v. Miles*, 360 F.3d 472, 480 (5th Cir. 2004) (AKS applies where item or service "could be paid for by a federal health care program"). Taken together, the phrase "payment may be made" means the AKS applies when payment under a federal health care program is contemplated, possible, or "could" be made.

Courts have suggested that the "payment may be made" language requires only a "minimal showing." *MedPricer.com, Inc. v. Becton, Dixon & Co.*, 240 F. Supp. 3d 263, 272–73 (D. Conn. 2017) (fact that syringes typically are not separately reimbursable by a federal health care program "does not foreclose a showing that 'payment may be made' under a federal health care program"); *see also In re EpiPen Direct Purchaser Litig.*, No. 20-cv-0827, 2021 WL 147166, at *14 (D. Minn. Jan. 15, 2021) (rejecting defendant's argument that plaintiffs "failed to draw a nexus to a federal healthcare program" because it was "reasonable to infer that federal health care programs 'may' pay for EpiPens"); *Schaeffer*, 328 F. Supp. 3d at 560 (agreeing with HHS-OIG that "carving out federal health care business from commercial referrals may violate the Anti-Kickback Statute").

Whatever its outer boundaries, the "payment may be made" requirement is plainly satisfied when items tainted by a kickback are "paid for" or "to be paid for" by a federal health care program. *E.g.*, *United States v. Howard*, 28 F.4th 180, 188–90 (11th Cir. 2022) (describing the TRICARE program and its coverage and payment for compound drugs and affirming AKS convictions for

the payment and receipt of kickbacks in connection with compound drugs "paid for" and "to be paid" for by TRICARE); *see also United States v. Ricard*, 922 F.3d 639, 647 (5th Cir. 2019) (AKS criminalizes the payment of funds or benefits designed to encourage the referral of services "to be paid for by the Medicare program"). Here, payment by TRICARE was not just a mere possibility. TRICARE paid hundreds of millions of dollars for compound claims containing PCCA's ingredients. Dkt. 66 ¶179. The "payment may be made" requirement is plainly satisfied.

PCCA's interpretation is objectively unreasonable because it is atextual, has no supporting case authority (as PCCA appears to concede—*see* Dkt. 84 at 51), and would lead to absurd results. The statutory text of the AKS does not say any "item *which is otherwise legally reimbursable* under a federal health care program," as PCCA would read the statute. Under PCCA's interpretation, the AKS would not apply to kickback schemes designed to induce federal payment for medically unnecessary items and services, certain off-label uses of drugs, and items or services that were not provided, which are also ineligible for reimbursement. The government has enforced the AKS in a wide range of kickback schemes designed to induce federal payment. *E.g.*, *Howard*, 28 F.4th at 180.

Under PCCA's reading, nothing would prevent a drug manufacturer from paying kickbacks to induce doctors to prescribe medically unnecessary drugs, while causing and intending federal health care programs to pay hundreds of millions of dollars for those prescriptions. According to PCCA's interpretation, both the manufacturer who paid the kickbacks and the doctor who received them could escape all civil and criminal AKS liability—even though the objective of the kickback scheme was to obtain federal payment—simply by showing (after the fact) that the drug was not medically necessary and therefore not "reimbursable." Congress did not intend to grant those who pay kickbacks in connection with federal health care programs such a "get out of jail free" card.

PCCA's citation to certain HHS-OIG advisory opinions is unavailing. Dkt. 84 at 51–52. Those advisory opinions "have no application to any individual or entity that does not join in the request for the opinion. No individual or entity other than the requestor(s) may rely on an advisory opinion." 42 C.F.R. § 1008.53. Moreover, those advisory opinions do not say that the AKS is limited to "covered" items. Rather, in each opinion, the proposed arrangement was not directed toward federal health care program business.[4] By contrast, PCCA directed its kickback scheme, at least in part, at TRICARE and caused TRICARE to pay hundreds of millions of dollars for kickback-tainted items.

ii. PCCA's Arguments Regarding TRICARE's Lack of Authority Are No Defense to Its AKS and FCA Violations.

PCCA also argues that TRICARE acted contrary to its regulations and lacked "authority to reimburse compounded medications containing bulk ingredients" because such ingredients were not FDA approved. Dkt. 84 at 30. Even if TRICARE's coverage of compounds containing bulk ingredients were contrary to its regulations, that would be no defense to the government's claims. *See United States ex rel. Ormsby v. Sutter Health*, 444 F. Supp. 3d 1010, 1068 (N.D. Cal. 2020) (invalidity of CMS payment methodology no defense to FCA action); *Cedars-Sinai Med. Ctr. v. Shalala*, 125 F.3d 765, 769 (9th Cir. 1997) ("Even if the Hospitals succeed in having the rule declared invalid . . . that will be no defense to the Relator's claims under the False Claims Act.").

PCCA's arguments are similar to those the Supreme Court has repeatedly rejected in criminal cases involving false or fraudulent statements to the government. *See Bryson v. United*

[4] HHS-OIG may analyze, among other things, the risk that a proposed arrangement may implicate a federal health care program or result in the over-utilization of items and services for which payment may be made by a federal health care program. *See* 42 C.F.R. § 1008.5. A particular advisory opinion's use of the phrase "reimbursable items or services" in that context does not limit the scope of the AKS's plain language and is based on the specific factual scenarios presented to OIG by the requester. *See id*. §§ 1008.53, 1008.59.

States, 396 U.S. 64, 67–69 (1969); *Dennis v. United States*, 384 U.S. 855, 867 (1966); *Kay v. United States*, 303 U.S. 1, 6 (1938); *United States v. Kapp*, 302 U.S. 214, 217–18 (1937). In *Bryson*, an individual who made false statements to the government in an affidavit required under the National Labor Relations Act attempted to have his conviction overturned by arguing that the affidavit requirement was constitutionally invalid. 396 U.S. at 67–68. Drawing upon a long line of cases, the Court rejected the argument:

> The governing principle is that a claim of unconstitutionality will not be heard to excuse a voluntary, deli[b]erate and calculated course of fraud and deceit. One who elects such a course as a means of self-help may not escape the consequences by urging that his conduct be excused because the statute which he sought to evade is unconstitutional.

Id. at 68. The Supreme Court held that the validity of the affidavit requirement was "legally irrelevant" as none of the elements of proof necessary for petitioner's conviction was "shown to depend on the validity of [the affidavit requirement]." *Id.* at 68–69; *accord Dennis*, 384 U.S. at 865–67 ("It is no defense to a charge based upon this sort of enterprise that the statutory scheme sought to be evaded is somehow defective.").[5]

Similarly, PCCA cannot escape the consequences of its fraud by arguing that TRICARE lacked authority to pay for its ingredients. TRICARE's supposed lack of authority is "legally irrelevant" and does not "excuse a voluntary, deli[b]erate and calculated course of fraud and

[5] PCCA's reliance on *Kelly v. Railroad Retirement Board*, 625 F.2d 486 (3d Cir. 1980) is misplaced. That case involved the denial of an application for benefits based on evidence that the claimant had no chance to rebut. *Kelly*, 625 F.2d at 491. The Third Circuit held that "[s]ince the Board did not comply with its regulations with respect to this 'evidence,' it is to be given no effect, and cannot be deemed 'evidence on the record' when we review the Agency's decision for substantial evidence." *Id.* at 492. Here, in contrast, PCCA was neither unaware of nor prejudiced by TRICARE's actions; rather, through its fraudulent conduct, it knowingly sought to enrich itself at TRICARE's expense.

deceit." *Bryson*, 396 U.S. at 68. None of the elements of the FCA or AKS in any way depend on the validity of TRICARE's authority to pay for bulk ingredients.[6]

Moreover, PCCA directed its fraudulent scheme at TRICARE and profited from TRICARE's payment for its ingredients. As has been long established by the Supreme Court, "[w]hen one undertakes to cheat the Government . . . by false statements, he has no standing to assert that the operations of the Government in which the effort to cheat or mislead is made are without . . . sanction." *Kay*, 303 U.S. at 6; *accord Kapp*, 302 U.S. at 217–18 ("It is cheating the government at which the [criminal false claims] statute aims and Congress was entitled to protect the government against those who would swindle it regardless of questions of constitutional authority as to the operations that the government is conducting. Such questions cannot be raised by those who make false claims against the government."); *see also United States v. Blair*, No. ELH-19-00410, 2021 WL 5040334, at *36 (D. Md. Oct. 29, 2021) (holding that the fact "TRICARE may have paid a claim erroneously would hardly justify the alleged conduct at issue" and collecting cases explaining that a victim's negligence is no defense to fraud).

II. The Government Adequately Pleaded Violations of the False Claims Act.

The FCA "was intended to reach all types of fraud, without qualification, that might result in financial loss to the Government." *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968). The FCA imposes liability on any person (1) who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or (2) who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)–(B). The government must plausibly allege four elements to establish an FCA

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[6] PCCA does not dispute that TRICARE had the authority to reimburse compound claims generally.

claim: "(1) there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due (i.e., that involved a claim)." *United States ex rel. Porter v. Magnolia Health Plan, Inc.*, 810 F. App'x 237, 240 (5th Cir. 2020) (quotations omitted).

A. The Government Adequately Pleaded Falsity.

i. PCCA Made Fraudulent Statements Material to False Claims.

To allege falsity under § 3729(a)(1)(B), the government must allege "the recording of a false record" that is material to a claim for payment. *Grubbs*, 565 F.3d at 193. The false statement need not be made to the government, so long as the defendant knew it would be material to a payment by the government. *See Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 671–72 (2008).[7] Where a company reports false prices "via the publishing compendium knowing that pharmacies would present claims to [the government] which will be reimbursed based on a formula that utilizes the inflated price to determine the appropriate reimbursement amount," this is sufficient to allege falsity. *See Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 145 (D. Mass. 2008) (discussing state FCA analog). The complaint alleges that here. PCCA reported fraudulently inflated AWPs, knowing they would be used to determine TRICARE reimbursement amounts. Dkt. 66 ¶¶53–64, 152–63.

1. PCCA Did Not Have Unfettered Discretion to Establish AWPs Bearing No Relationship to Actual Prices.

AWP is a standard pricing metric published in commercial drug pricing compendia based on information submitted by manufacturers or suppliers like PCCA. *See* Dkt. 66 ¶¶2, 53–55.

[7] Although *Allison Engine* discussed whether the statement was made "to get" the Government to pay a claim, Congress amended the FCA in response, and the relevant question is now whether the statement was material. *United States ex rel. Int'l Brotherhood of Electrical Workers Local Union No. 98 v. Farfield Co.*, 5 F.4th 315, 324 (3d Cir. 2021).

AWPs are commonly used by both government health care programs and commercial insurance companies as benchmarks in determining reimbursement amounts for drug products. *See id.* ¶¶1–2, 54. PCCA argues that its AWPs cannot be false—no matter how divorced from its actual prices—because there is no statutory or regulatory "definition." Dkt. 84 at 1. But the absence of a specific definition for AWP does not grant companies unfettered discretion to use AWPs as an instrument of fraud. Courts have routinely recognized that when AWPs are fictitious numbers bearing no rational relationship to any actual price, they are false or fraudulent.

For example, in *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 582 F.3d 156, 178–84 (1st Cir. 2009), the First Circuit affirmed the district court's ruling that AWPs reported by a pharmaceutical manufacturer with spreads greater than 30% were unfair and deceptive under state consumer protection laws. The court noted that the use of AWP, without definition, in the Medicare reimbursement scheme did not grant the pharmaceutical industry "free reign over drug pricing" or "unfettered discretion to report drug prices that bear no relation to products' actual prices." *Id*. at 170–71 nn.9–10; *see also In re Pharm. Indus. AWP Litig.*, 478 F. Supp. 2d 164, 173–74 (D. Mass. 2007) ("Defendants' interpretation that they have *carte blanche* to publish sky-high prices unmoored from the acquisition costs of providers leads to absurd results.").

Similarly, in *In re Lupron Marketing and Sales Practices Litigation*, 295 F. Supp. 2d 148, 167 (D. Mass. 2003), the court refused to dismiss RICO claims based on fraudulent AWPs, explaining that the "defendants trumpeted a lie by publishing the inflated AWPs, knowing (and intending) them to be used as instruments of fraud." The court rejected the defendants' argument (like PCCA's) that there was widespread knowledge that AWP was a "'sticker price' and never

intended to reflect the drug's true average wholesale price." *Id.* at 168 n.19. The court noted that the 300% markup at issue was not "modest," and that a "sticker price" is not a "sucker price." *Id.*

Other courts have agreed. *E.g.*, *United States ex rel. Rahimi v. Zydus Pharm., Inc.*, No. 15-6536-BRM-DEA, 2017 WL 1503986, at *11 (D.N.J. Apr. 26, 2017) ("[C]ourts have consistently rejected the notion that AWPs can be defined as whatever price drug manufacturers chose to publish through pricing compendia."); *In re Miss. Medicaid Pharm. Average Wholesale Price Litig.*, 190 So. 3d 829, 838–39 (Miss. 2015) (affirming drug manufacturer's liability for common law fraud based on AWPs that were inflated by 886% and which were "fictitious and assigned solely for the purpose of creating a fraudulent profit margin"); *New York v. Pharmacia Corp.*, 895 N.Y.S.2d 682, 695 (N.Y. Sup. Ct. 2010) (rejecting theory that "AWP means whatever price is published" and that drug manufacturers could "unilaterally establish whatever 'spread' they desire").

PCCA reported AWPs ranging from 1,300% to over 56,000% of its selling prices. Dkt. 66 ¶62. These spreads are far more egregious than those in the cases cited above. PCCA reported these false AWPs to create a fraudulent spread for its customers and with the knowledge that TRICARE would use them to determine reimbursements. *Id.* ¶¶53–64. In short, PCCA "trumpeted a lie" and used its AWPs as an "instrument of fraud." *Lupron*, 295 F. Supp. 2d at 167.

PCCA erroneously asserts that the government's "stated position" is that "an AWP that is 3000% of an active pharmaceutical ingredient's acquisition cost is 'fraudulently inflated' while one that is 1500% of that acquisition cost is not fraudulent." Dkt. 84 at 7, 14. That is not the government's position. The complaint cites fraudulently inflated AWPs that were 1,300% of PCCA's selling prices and above. Dkt. 66 ¶61–62. And the complaint notes that PCCA's AWPs were "already inflated" prior to the substantial increases in March 2012. *Id.* ¶138. The government

simply limited the claims in this action, which already amount to hundreds of millions of dollars in inflated TRICARE reimbursements. *Id.* ¶¶1, 16, 173, 179. The Court should reject any inference that by focusing its complaint on certain conduct within a specific timeframe, the government deemed PCCA's AWPs outside that timeframe "reasonable" or "non-fraudulent."

None of the cases cited by PCCA support its contention that comparing AWPs with actual sales prices is "wholly meaningless." Dkt. 84 at 6. In *State of Louisiana v. United States Department of Health & Human Services*, 905 F.2d 877, 881 (5th Cir. 1990), the court simply upheld HHS's rejection of a state Medicaid agency's use of AWP as its "closest estimate" of "estimated acquisition costs" under Medicaid regulations. While the case suggested that AWPs do not always *equate* to actual prices because of commonly available discounts, *id.* at 880, it did not say that the correlation is "wholly meaningless."

In *Sandoz Inc. v. Commonwealth ex rel. Conway*, 405 S.W.3d 506, 511 (Ky. Ct. App. 2012), the court stated that "there was ample evidence from which the jury could have properly determined that [defendant] did, in fact, submit AWPs in a false, misleading, or deceptive manner." The crux of the court's judgment for defendant was that the Commonwealth was "aware of the degree of inflation" and acted to "protect" those inflated reimbursements. *Id.* That is not the case here. In *Commonwealth v. TAP Pharmaceutical Products, Inc.*, 94 A.3d 350, 361–63 (Pa. 2014), the court reversed the lower court's judgment, which held defendants liable for deceptive practices, because the court failed to consider rebates the defendants paid to the program when determining damages—also not an issue here.

PCCA also cites to a 2002 GAO report containing a single statement that a "manufacturer is free to set an AWP at any level." Dkt. 84 at 26 (quoting GAO 02-969T). The statement comes from a footnote containing no substantive discussion of AWP beyond a very general description—

i.e., that it is "often described as a 'list price'" and may not reflect the actual price paid by purchasers. *Id*. at Ex. 2 at 5. The footnote is hardly an authoritative statement that companies like PCCA have unfettered discretion to set AWPs at egregiously inflated levels and market the resulting spreads without legal repercussion. They clearly do not, as warned by the OIG Guidance and cases cited above, all of which post-date the 2002 GAO report.

2. PCCA's AWPs Are Actionable Misrepresentations.

PCCA's AWPs also constitute actionable misrepresentations under *Escobar* because they omit important qualifying information. The FCA's reference to "false" and "fraudulent" claims incorporates the common law meaning of those terms. *Escobar*, 579 U.S. at 187. In *Escobar*, the Court held that falsity includes not only "express" or "affirmative" falsehoods, but also misrepresentations resulting from misleading "half-truths," i.e., "representations that state the truth only so far as it goes, while omitting critical qualifying information." *Id.* at 188. "A statement that misleadingly omits critical facts is a misrepresentation irrespective of whether the other party has expressly signaled the importance of the qualifying information." *Id.* at 191.

PCCA omitted critical facts about its AWPs (that they were marked up thousands of percent over actual selling prices) and misleadingly implied facts PCCA knew were untrue. Even if AWP is understood to be a "list price," "sticker price," or "suggested retail price," as PCCA suggests, an AWP of $818.68 per gram for resveratrol, for example, implies an actual selling price far greater than $1.77. Dkt. 66 ¶61. As the *Mylan* court observed, "spreads that were almost always greater than 50%, consistently greater than 100%, sometimes greater than 1000%, and occasionally greater than 10000% . . . could hardly even be called true list prices; undoubtedly a consumer would be surprised to find that most purchasers could acquire a car for one-half the sticker price, let alone for a hundredth of it." 608 F. Supp. 2d at 154.

In *Lupron*, the court found inflated AWPs to constitute the kind of misleading half-truths later discussed in *Escobar*. 295 F. Supp. 2d at 165–68. There, the defendants allegedly inflated the AWP of an injectable drug, explained how doctors could "profit from the spread," increased the drug's AWP to counter a competitor's AWP, and counseled doctors to conceal their actual invoice costs from Medicare and other insurance carriers. *Id.* at 161. The court explained: "[w]hether one views the defendants' actions as involving the dissemination of information that was wholly false, or false because of an incomplete depiction of the truth, they are actionable[.]" *Id*. at 167; *see also Massachusetts v. Mylan Labs.*, 357 F. Supp. 2d 314, 321 (D. Mass. 2005) ("half-truths may be as actionable as whole lies").

Here, PCCA reported AWPs knowing TRICARE would use them to determine reimbursement amounts. Dkt. 66 ¶5. PCCA inflated its AWPs by thousands of percent over its actual selling prices to increase its customers' profits. *Id.* ¶¶8, 61. And PCCA sought to conceal those spreads, fearing a "disaster waiting to happen." *Id.* ¶156. Like PCCA, the *Lupron* defendants argued that they could not be liable because "everyone" knew AWPs often exceeded actual acquisition costs. But the court rejected that argument, noting: "[I]f everything . . . was known to everybody, why did [d]efendants emphasize secrecy?" *Lupron*, 295 F. Supp. 2d at 168 n.19.

ii. PCCA Caused the Submission of False or Fraudulent Claims for Payment.

1. PCCA Engaged in a Fraudulent Course of Conduct.

As described in the Factual Background, the complaint more than plausibly alleges PCCA engaged in a "fraudulent course of conduct" by reporting fraudulent AWPs, marketing the resulting mega-spreads, promoting high-AWP formulas, holding seminars where it taught customers how to "work the spread," and concealing its selling prices. *See United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 467 (5th Cir. 2009); *see also Pharm. Indus.*,

582 F.3d at 199 (pharmaceutical company "unfairly and deceptively published an artificial average wholesale price" where there was a "scheme to maximize the divergence of the AWP from actual acquisition cost"); *In re Miss. Medicaid*, 190 So. 3d at 838–39 (affirming drug manufacturer's liability for common law fraud based on AWPs that were "fictitious and assigned solely for the purpose of creating a fraudulent profit margin"); *Virginia v. McKesson Corp.*, No. C 11–02782 SI, 2011 WL 4853369, at *3 (N.D. Cal. Oct. 13, 2011) (complaint alleged a "fraudulent scheme" where it alleged that defendant increased AWP spreads and sought to take advantage by communicating AWP changes to customers).

PCCA suggests it could have believed that compounds containing its ingredients "could not result in reimbursement by TRICARE." Dkt. 84 at 42. But as discussed above, the complaint alleges that PCCA knew TRICARE reimbursed its customers for claims with its ingredients and actively sought to delay TRICARE changes to its reimbursement policies. Dkt. 66 ¶¶ 5, 118, 159, 162. A motion to dismiss is not the appropriate forum to dispute those facts.

2. PCCA's AKS Violations Establish Falsity as a Matter of Law.

As also discussed above, PCCA violated the AKS by marketing its inflated AWPs and AWP spreads and offering customers other benefits like all-expense-paid vacations. The AKS expressly provides that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). A claim submitted to a federal health care program "that results from or is tainted by a kickback is a false claim under the FCA as a matter of law." *Wheeler*, 2019 WL 571349, at *5.[8] TRICARE claims tainted by PCCA's AKS violations are *per se* false under the FCA.

[8] *See also United States ex rel. Lutz v. Mallory*, 988 F.3d 730, 741 (4th Cir. 2021); *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019).

iii. Although Falsity Is Not Limited to "Objective Falsehoods," PCCA's AWPs Were Objectively False.

PCCA argues that the FCA requires "objective" falsehoods. Dkt. 84 at 12–15. The FCA contains no such requirement, and neither the Supreme Court nor the Fifth Circuit have adopted such a standard.[9] Indeed, the Fifth Circuit recently rejected an "objective falsity" standard in the context of a criminal health care fraud case. *See United States v. Mesquias*, 29 F.4th 276, 282–83 (5th Cir. 2022). There, the defendants argued that "clinical judgments, like the ones underlying hospice and home health certifications, cannot be the basis of a fraud prosecution unless the government offers expert testimony to prove them objectively false." *Id.* at 282. The Fifth Circuit rejected this argument, explaining that "health care providers cannot immunize themselves from prosecution by cloaking fraud with a doctor's note" and "[c]ategorical evidentiary requirements are at odds with a jury's ability to consider a broad array of direct and circumstantial evidence." *Id.*

Similarly, an objective falsity requirement is "inconsistent with the [FCA.]" *United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89, 95 (3d Cir. 2020); *accord United States ex rel. Winter v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108, 1119 (9th Cir. 2020). The Supreme Court has cautioned against "adopting a circumscribed view of what it means for a claim to be false or fraudulent." *Escobar*, 579 U.S. at 192 (quotations omitted). Limiting the FCA to "objective" falsehoods would adopt a "circumscribed view" of falsity inconsistent with *Escobar*.

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[9] PCCA cites *United States ex rel. Barron v. Deloitte & Touche, LLP*, No. SA-99-CA-1093-FB, 2009 WL 10670806, at *11–12 (W.D. Tex. Feb. 11, 2009), report and recommendation adopted, No. SA-99-CA-1093-FB, 2009 WL 10670807 (W.D. Tex. Mar. 26, 2009), a pre-*Escobar* decision, to suggest objective falsity is required in this district. This case is inapposite because the court's decision rested on the relator's inability to identify at summary judgment a single "specific claim" that was false or fraudulent. *Id.* at *12.

Moreover, courts have typically discussed the concept of objective falsity in cases involving "opinions," clinical or scientific "judgments," or prospective "estimates."[10] Even then, courts have recognized that opinions and estimates can be fraudulent where they imply the existence of facts that do not exist or where they are not honestly held. *See Winter*, 953 F.3d at 1117; *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 792 (4th Cir. 1999); *United States ex rel. USN4U, LLC v. Wolf Creek Fed. Servs., Inc.*, No. 20-4246, 2022 WL 1531966, at *4 (6th Cir. May 16, 2022).

PCCA's AWPs were not based on opinions, judgments, or estimates. Rather, they were made up numbers, inflated from 13 to more than 500 times PCCA's actual selling prices, to drive sales of its ingredients. *See* Dkt. 66 ¶¶10, 61–62. As such, PCCA's AWPs were objectively false. PCCA does not point to a single case where a court found AWPs like those here to be non-fraudulent. On the contrary, many courts have found far smaller spreads to be false, fraudulent, deceptive, and misleading. PCCA itself did not believe its AWPs were proper because it actively sought to conceal its AWP spreads, knew that "ridiculous" AWP inflation would bring audits and investigations, and recognized that it was setting AWPs well above what they "should be." *See id.* ¶¶66–68, 70, 85–86, 153–57. Under these circumstances, PCCA's egregiously inflated AWPs were objectively false and fraudulent.

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[10] The cases PCCA cites are distinguishable. *See United States v. AseraCare, Inc.*, 938 F.3d 1278, 1301 (11th Cir. 2019) (reasonable difference of opinion between physicians without more did not establish falsity); *United States ex rel. Wilson v. Kellogg Brown Root, Inc.*, 525 F.3d 370, 377 (4th Cir. 2008) (relator alleged defendant failed to comply with "relatively vague" contractual provisions, and government had not expressed dissatisfaction); *United States ex rel. DRC, Inc. v. Custer Battles, LLC*, 472 F. Supp. 2d 787, 798 (E.D. Va. 2007), *aff'd*, 562 F.3d 295 (4th Cir. 2009) (no false statement regarding estimated number of personnel where defendant did not commit to fixed number); *United States ex rel. Dekort v. Integrated Coast Guard Sys.*, 705 F. Supp. 2d 519, 536 (N.D. Tex. 2010) (same where defendant persuaded Coast Guard to adopt more favorable guidance language in lieu of mandatory requirements during contract negotiations).

iv. PCCA Is Liable Regardless of Certification.

According to PCCA, the complaint fails to plead an express or implied "false certification." Dkt. 84 at 18–19. Although such certifications can establish FCA liability, they are not required. PCCA's fraudulent AWPs, which were material to TRICARE's payment of claims, are themselves sufficient to establish liability. In addition, claims tainted by AKS violations are false *per se*. Nevertheless, when PCCA's customers submitted claims to TRICARE, they impliedly certified compliance with material statutory, regulatory, and contractual requirements, including the AKS. PCCA's fraudulent conduct caused those certifications to be false.

1. PCCA's False Statements Are Sufficient to Establish Falsity.

"The recording of a false record, when it is made with the requisite intent, is enough to satisfy the [FCA]" so long as the false record is material to payment. *Grubbs*, 565 F.3d at 193. The government need not allege that there was also a false certification. *See United States ex rel. Jamison v. Career Opportunities, Inc.*, No. 3:16-CV-3248-S, 2020 WL 520590, at *2, 4–6 (N.D. Tex. Jan. 31, 2020) (where defendant allegedly recorded false data used on reimbursement forms submitted to DOL, allegations sufficiently stated presentment of false claims and false statements material to false claims, even though claims did not include any "certification" that the information was "true and correct"). Likewise, the government need not allege that "PCCA ever certified that its AWPs were accurate." Dkt. 84 at 19.

2. AKS Violations Are False *Per Se* Regardless of Certification.

PCCA contends that a certification is "still required to establish liability under the FCA for an AKS violation, even though an AKS violation may be an FCA violation as a matter of law." Dkt. 84 at 20. But under the statute, an AKS violation establishes falsity under the FCA without any additional certification. 42 U.S.C. § 1320a-7b(g). "The statute's use of the term 'constitutes' would be meaningless if courts had" to inquire "into whether the entity submitting the claim had

certified its compliance with the AKS." *Guilfoile*, 913 F.3d at 190; *see also United States v. Vora*, 488 F. Supp. 3d 554, 566 (W.D. Ky. 2020) (certification not required).

PCCA misreads *Marlin Medical*. Dkt. 84 at 20. There, the court determined that the government "stated with particularity an AKS violation, and thus has established the falsity of the submitted claims[,]" without requiring any certification. *Marlin Med.*, 2022 WL 190308, at *7. PCCA also cites *United States ex rel. Nunnally v. West Calcasieu Cameron Hospital*, 519 F. App'x 890 (5th Cir. 2013), which addressed conduct predating the enactment of § 1320a-7b(g). And the crux of the court's decision there was simply that to establish FCA liability for an AKS violation, there must have been a claim. *Nunnally*, 519 F. App'x at 894.

3. PCCA Caused the Submission of Implied False Certifications.

PCCA's fraudulent conduct caused its customers to submit TRICARE claims that impliedly and falsely certified compliance with the AKS, TRICARE's regulations, and ESI's provider agreements. Liability under an "implied false certification theory" attaches "at least" where a claim "makes specific representations about the goods or services provided", and "failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Escobar*, 579 U.S. at 190.

PCCA customers' claims to TRICARE contained several representations about the specific ingredients used and pricing information for each ingredient. Dkt. 66 ¶¶42, 44–45. Those claims did not disclose that the AWPs for those ingredients were egregiously inflated by thousands of percent over selling prices and that they were tainted by kickbacks. *See id.* ¶¶64, 191. These are actionable misrepresentations. *See Escobar*, 579 U.S. at 189–90 (claims conveyed codes corresponding to specific services and providers without disclosing that providers did not comply with the state's Medicaid requirements); *United States ex rel. Campbell v. KIC Dev., LLC*, No. EP-18-CV-193-KC, 2019 WL 6884485, at *9 (W.D. Tex. Dec. 10, 2019) ("Defendants specifically

represented that they had installed skylights and renovated buildings as agreed, but they failed to disclose that they had done that work at far greater profit than permitted by law, by virtue of an unlawful bribery scheme.”).

These misrepresentations were relevant to material statutory, regulatory, and contractual requirements. The claims violated TRICARE’s fraud and abuse regulations, which explicitly prohibit arrangements between a supplier (like PCCA) and provider (like PCCA’s customers) that result in unnecessary costs or charges to TRICARE or that include kickback arrangements designed to overcharge TRICARE. Dkt. 66 ¶¶165–67 (citing TRICARE regulations). Those regulations also prohibit billing at rates substantially in excess of customary or reasonable charges. *Id*. ¶167. Violations may result in the denial of claims or a provider’s exclusion or suspension from TRICARE. *Id*. ¶165. Further, TRICARE only reimburses for reasonable and necessary items and services and requires providers to furnish items and services economically. *Id*. ¶169. The government alleges that PCCA caused unnecessary and grossly excessive charges due to its fraudulently inflated AWPs and kickbacks. *E.g.*, *id*. ¶¶1, 4, 8, 15–16. Furthermore, as a result of PCCA’s inflated AWPs, its customers’ claims violated explicit contractual requirements that compound claims not be submitted to ESI—TRICARE’s pharmacy benefit manager—with inflated AWPs or for amounts in excess of the pharmacy’s acquisition costs, taking into account a reasonable markup. *Id.* ¶¶41, 47.[11]

PCCA emphasizes that it did not submit claims to the government. Dkt. 84 at 19. This is irrelevant as the FCA reaches anyone who “causes” the submission of a false claim or who makes or causes to be made or used a false statement material to a false claim. 31 U.S.C.

[11] Contrary to PCCA’s argument (Dkt. 84 at 42), the government is not required to plead that PCCA had access to ESI’s contracts or manuals. The complaint need only allege plausibly that PCCA caused its customers to submit claims that violated these material requirements.

§ 3729(a)(1)(A)–(B). Thus, "a person need not be the one who actually submitted the claim forms in order to be liable." *United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 378 (5th Cir. 2004) (quotations omitted); *see also Peterson v. Weinberger*, 508 F.2d 45, 52 (5th Cir. 1975) (FCA was designed to "reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud"). Through its fraudulent AWPs and kickbacks, PCCA knowingly caused the claims at issue here to be false. *See Mylan*, 608 F. Supp. 2d at 145.[12]

v. The Government Tied PCCA's Conduct to Paid TRICARE Claims.

PCCA asserts that the government did "not sufficiently tie PCCA's alleged misconduct to any actual claims." Dkt. 84 at 15. The complaint satisfies the particularity requirements of Rule 9(b) by alleging "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Grubbs*, 565 F.3d at 190.

As detailed above, the complaint describes PCCA's fraudulent conduct and identifies 325 examples of false and fraudulently inflated compound claims submitted to TRICARE containing PCCA ingredients. The complaint further alleges that each of these compound claims was reimbursed at thousands of dollars per prescription. *See* Dkt. 66 at ¶123 & Ex. 22 (examples). Exhibit 22 identifies specific details about these inflated claims, including: (1) the date dispensed; (2) the submitting customer's name; (3) customer location; (4) the specific PCCA ingredients contained within each claim and corresponding NDC number; and (5) amount paid by TRICARE along with payment date.[13]

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[12] PCCA's contention that it is not "obligated" to report AWPs is unavailing. Dkt. 84 at 19. PCCA chose to report AWPs, knowing that they would be used to determine TRICARE reimbursement to its customers. "[I]f the defendant does speak, he must disclose enough to prevent his words from being misleading." *Escobar*, 579 U.S. at 188 n.3 (quotations omitted).

[13] PCCA states that Exhibit 22 identified eight claims paid in the year 1900. *See* Dkt. 84 at 31 n.9. TRICARE paid the claims in 2013. The complaint alleges that PCCA's fraudulent conduct,

This specificity exceeds Rule 9(b)'s requirements. As the Fifth Circuit has explained, "a plaintiff does not necessarily need the exact dollar amounts, billing numbers, or dates to prove to a preponderance that fraudulent bills were actually submitted." *Grubbs*, 565 F.3d at 190. "To require these details at pleading is one small step shy of requiring production of actual documentation with the complaint, a level of proof not demanded to win at trial and significantly more than any federal pleading rule contemplates." *Id.*

PCCA asserts that "the government does not plead that any of the claims referenced in Exhibit 22 . . . were submitted and paid based on the AWP for the ingredients listed." Dkt. 84 at 15. This is incorrect. The complaint alleges that the examples consist of "inflated compound prescription claims submitted to TRICARE for . . . PCCA ingredients." Dkt. 66 ¶123. The complaint further alleges that "[a]s a result of PCCA's actions as alleged in this complaint," namely its AWP inflation, "TRICARE paid hundreds of millions of dollars in excess reimbursement for tens of thousands of false and fraudulent compound prescription claims containing PCCA ingredients submitted by PCCA's customers. Examples are included in Exhibit 22." *Id.* ¶179. It is thus reasonable to infer that the claims identified in Exhibit 22 were reimbursed based on PCCA's AWPs, an inference further supported by the inflated amounts of the claims.

PCCA claims that it "is not on sufficient notice of what specific claims and what specific portions of those claims, are alleged to be fraudulent." Dkt. 84 at 17. The complaint provides specific details of PCCA's fraudulent scheme; identifies specific PCCA ingredients with grossly inflated AWPs; and provides 325 examples of false and fraudulently inflated compound claims

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including these examples, occurred between 2012 and 2015. *See* Dkt. 66 ¶¶1, 123. Even if the Court did not consider the eight claims, the complaint would still be sufficient.

containing those ingredients submitted to, and paid by, TRICARE. Rule 9(b) does not require the government to identify what "portion" of these claims are fraudulent.

B. The Government Adequately Pleaded Materiality.

The FCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). A matter is material if: (1) a reasonable person would attach importance to it in determining a "choice of action," or (2) "the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter in determining his choice of action," whether or not a reasonable person would do so. *Escobar*, 579 U.S. at 193 (quotations and citation omitted); *accord United States ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645, 661 (5th Cir. 2017) (requiring proof only that the defendant's false statements "had the 'potential' to influence the government's decision, not that the false statements actually did so" (quoting *Longhi*, 575 F.3d at 469)).

Escobar identified several non-dispositive factors relevant to the materiality inquiry: whether the government has designated compliance with a particular "requirement as a condition of payment"; whether the violation of that requirement goes to the "essence of the bargain" or is "minor or insubstantial"; and whether the government acted when it had actual knowledge of similar violations. 579 U.S. at 193–95. "No one factor is dispositive, and our inquiry is holistic." *United States ex rel. Lemon v. Nurses To Go, Inc.*, 924 F.3d 155, 161 (5th Cir. 2019). Because the inquiry is holistic, it is often a matter for the jury. *E.g.*, *United States v. Hodge*, 933 F.3d 468, 474 (5th Cir. 2019) (affirming denial of motion for judgment). Even when materiality is assessed as a matter of law, no single factor is dispositive. *E.g.*, *Harman*, 872 F.3d at 665.

i. The Complaint Satisfies the Materiality Standard.

1. PCCA's Fraudulent Conduct Is Material under the FCA's Definition.

The government alleges that PCCA inflated the AWPs for its ingredients, and those AWPs impacted TRICARE's payment for compound claims containing those ingredients. *See* Dkt. 66 ¶¶1, 5, 55–56. PCCA's AWPs had a "natural tendency to influence . . . the payment or receipt of money" from TRICARE and were, therefore, material. *See* 31 U.S.C. § 3729(b)(4) (defining materiality under the FCA); *see also United States ex rel. Ven-A-Care v. Actavis Mid Atl. LLC*, 659 F. Supp. 2d 262, 271 (D. Mass. 2009) ("Reporting false AWPs had a natural tendency to influence the Government's actions, by inflating the amount of the Government's payment." (quotations and alteration marks omitted)); *Mylan*, 608 F. Supp. 2d at 153 ("Reporting false [wholesale acquisition costs] had a natural tendency to influence the [state's] actions, by inflating the amounts used to compute [estimated acquisition cost], and thus potentially the amount of the [state's] payment."). Furthermore, a reasonable person would attach importance to the price paid in a transaction, particularly where, as here, the price is inflated. *See KIC*, 2019 WL 6884485, at *12 ("Because 'a reasonable person would attach importance to' the price of a contract that he or she enters, the Government has adequately alleged materiality.").

The government further alleges PCCA knew its AWPs were material to payments by payers like TRICARE. *See* Dkt. 66 ¶¶152–57. PCCA was concerned that disclosure of its selling prices in comparison to its AWPs could lead payers like TRICARE to discontinue paying for compound claims and knew that a payer had done so. *See id.* ¶154. Therefore, PCCA implored its customers never to disclose PCCA's selling prices to auditors because disclosure will "create huge problems for you" and is "a disaster waiting to happen." *Id.* ¶156. PCCA knew or had reason to know that the government attached importance to PCCA's spreads. *See Marlin Med.*, 2022 WL

190308, at *8 (AKS violations inherently material and "could have had the potential to influence the government's decisions" (quotations omitted)). Because the government sufficiently alleged materiality under the statutory definition, the Court should reject PCCA's arguments that the government cannot establish materiality.

2. PCCA's Fraudulent Conduct Is Also Material under *Escobar*.

In *Lemon*, the Fifth Circuit reversed the district court's dismissal because relators sufficiently alleged materiality under the *Escobar* factors. 924 F.3d at 164. Specifically, the relators alleged that defendants fraudulently certified compliance with statutory and regulatory requirements, which were conditions of payment. *Id*. at 161. The alleged violations were "not minor" because they may have led "the government to make a payment which it would not otherwise have made." *Id*. at 163. And the government had taken criminal and civil enforcement actions in similar circumstances. *Id*. at 162. As in *Lemon*, the government sufficiently pleaded materiality under each *Escobar* factor here.

Conditions of Payment. "[I]f a requirement is labelled a condition of payment and it is violated, that alone does not conclusively establish materiality. But it is certainly probative evidence of materiality." *Lemon*, 924 F.3d at 161 (quotations omitted); *see also United States ex rel. Bibby v. Mortgage Inv'rs Corp.*, 987 F.3d 1340, 1347 (11th Cir. 2021) (factor weighed in favor of materiality where "a lender's truthful certification that it charged only permissible fees was a condition of" payment on loan guaranties); *United States ex rel. Frey v. Health Mgmt. Sys., Inc.*, No. 3:19-CV-0920-B, 2021 WL 4502275, at *12 (N.D. Tex. Oct. 1, 2021) ("Relator's allegation of Defendant's failure to timely collect or collect reimbursement from liable third parties establishes a condition of payment."). *Cf. Marsteller for Use & Benefit of United States v. Tilton*,

880 F.3d 1302, 1313 (11th Cir. 2018) ("express condition of payment" is not required "for liability to attach").

As explained above, the government alleges PCCA caused its customers to violate the following conditions of payment: (1) the AKS; (2) fraud and abuse regulations prohibiting kickbacks and excessive, unnecessary, and unreasonable charges to TRICARE; and (3) requirements that compound claims not be submitted with inflated AWPs. Dkt. 66 ¶¶47, 165–69 (TRICARE regulations); *see also id*. ¶¶1, 4, 8, 16 (PCCA caused unnecessary and excessive charges and engaged in illegal kickbacks). This *Escobar* factor weighs in favor of materiality.

Essence of the Bargain and neither Minor nor Insubstantial. Courts "consider the extent to which the requirement that was violated is central to, or goes to the very essence of, the bargain." *Mortgage Inv'rs*, 987 F.3d at 1347–48 (quotations and alteration marks omitted); *see KIC*, 2019 WL 6884485, at *12 (allegations concerned "quintessentially material contract term that goes to the 'very essence of the bargain': price" (citation omitted)); *Frey*, 2021 WL 4502275, at *12 (government would attach importance to "a large sum of money"). Conversely, "[i]f the noncompliance was merely minor or insubstantial, then the noncompliance would be unimportant to the Government." *Id*.

PCCA's fraudulent conduct went to the essence of the bargain and was significant. PCCA's scheme was neither an innocent mistake nor unwitting non-compliance with minor or trivial requirements, but rather caused knowing and repeated violations of fraud and abuse regulations and other requirements central to TRICARE. *See* Dkt. 66 ¶¶1–16, 169. PCCA's actions caused TRICARE to pay hundreds of millions of dollars in excess reimbursements, while PCCA directly profited from its scheme. *Id.* ¶¶158, 179. PCCA's fraud cannot be called minor or insubstantial.

Government Action. "[P]roof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Escobar*, 579 U.S. at 194–95. "Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated," or "regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position," that is "very strong evidence that those requirements are not material." *Id.* at 195.

For this factor to be probative of immateriality, the government must have "actual knowledge that certain requirements were violated." *Id.* Actual knowledge of violations is not the same as awareness of allegations of violations. *See United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 112 (1st Cir. 2016); *United States ex rel. Montcrieff v. Peripheral Vascular Assocs., P.A.*, 507 F. Supp. 3d 734, 766 (W.D. Tex. 2020) ("It is not enough that the agency is aware of allegations of fraud, it must be aware of the fraud itself."), *on reconsideration in part*, No. SA-17-CV-00317-XR, 2022 WL 80293 (W.D. Tex. Jan. 7, 2022). Government action in response to fraud weighs in favor of materiality. *See United States v. Luce*, 873 F.3d 999, 1009 (7th Cir. 2017) (material as a matter of law where government debarred defendant for noncompliance); *Mortgage Inv'rs*, 987 F.3d at 1351–52 (fact issue where government knew of noncompliance and took actions); *United States ex rel. Mitchell v. CIT Bank, N.A.*, No. 4:14-CV-00833, 2022 WL 812364, at *13 (E.D. Tex. Mar. 16, 2022) (same where government refused to pay claims when it had knowledge of similar violations).

Here, TRICARE "signaled [a] change in position" and acted when it had sufficient knowledge of fraud. *See Escobar*, 579 U.S. at 195. The complaint states that PCCA engaged in

its fraudulent conduct from March 2012 to May 2015. Dkt. 66 ¶1. In March 2014, the relator filed his complaint in this matter, alleging that PCCA violated the FCA and AKS through its AWP inflation. Dkt. 1 ¶¶ 8, 199–210. TRICARE took action to curtail payment for compound claims even as PCCA lobbied against changes to TRICARE's reimbursement policies. Dkt. 66 ¶¶159–60. In November 2014, the DOD P&T Committee "unanimously recommended a prior authorization process for compound prescription claims." *Id.* ¶160. Following input from the Beneficiary Advisory Panel, TRICARE approved enhanced electronic screening and prior authorization, effective on May 1, 2015. *Id*. ¶161.

Because of TRICARE's action, "the number of compound claims to TRICARE declined sharply," and "PCCA's sales plummeted." *Id.* ¶161–62, 172. In addition, the government "has used the FCA to recover from other compound ingredient suppliers for monies TRICARE paid for compound ingredients with grossly inflated AWPs." *Id.* ¶174 (settlement with another supplier). Like the other *Escobar* factors, the government action factor favors materiality—which the complaint adequately pleads.

3. PCCA's Violations of the AKS Are Also *Per Se* Material.

Numerous courts, including this one, "have found AKS violations to be inherently material to the government's decision to pay claims presented." *Marlin Med.*, 2022 WL 190308, at *8 (quotations and alteration marks omitted); *accord Wheeler*, 2019 WL 571349, at *7 (failure to disclose AKS violation was "material omission"). Under *Escobar*, a violation of a federal criminal law designed to prevent fraud in federally funded health care programs is indisputably material to the government's payment decisions. *See United States ex rel. Capshaw v. White*, No. 3:12-CV-4457-N, 2018 WL 6068806, at *4 (N.D. Tex. Nov. 20, 2018); *United States v. Berkeley Heartlab, Inc.*, No. CV 9:14-230-RMG, 2017 WL 6015574, at *2 (D.S.C. Dec. 4, 2017). And 42 U.S.C. § 1320a-7b(g) makes "clear that compliance with the AKS is a precondition to the payment of claims

submitted to these programs." *Berkeley*, 2017 WL 6015574, at *1. Violations of the AKS are material because Congress has decreed that they are material. *See Guilfoile*, 913 F.3d at 190–91.

ii. PCCA's Counterarguments Regarding Materiality Are Irrelevant, Incorrect, or Unavailing.

Claimed Lack of Authority. PCCA contends, "[t]he government fails to plead how PCCA's reported AWPs could be material to TRICARE's payment decision, when its decision to reimburse compounded medications containing PCCA's products violated its own codified regulations." Dkt. 84 at 2. PCCA fails to explain how TRICARE's allegedly erroneous payment for PCCA's ingredients has any bearing on any of the *Escobar* factors or otherwise negates materiality. By paying for compounds containing bulk ingredients, TRICARE condoned neither PCCA's price inflation nor its kickbacks. Further, any erroneous payment by TRICARE does not legally excuse PCCA's fraudulent conduct, which remains material for the reasons stated above.

Claimed Continued Payment. PCCA asserts that "[t]he government knew the details of the alleged misconduct and continued to pay." Dkt. 84 at 25. PCCA also contends that Exhibit 22 "clearly shows that, even after the issuance of the" 2014 GAO report, "TRICARE continued to reimburse the exact same compounds identified in the report." *Id*. at 29. But TRICARE "signaled [a] change in position." *Escobar*, 579 U.S. at 195. Just one month after the October 2014 GAO report, the P&T Committee unanimously recommended that TRICARE implement certain controls on compound claims. *See* Dkt. 66 ¶160. After taking required steps, TRICARE implemented these controls effective May 2015, sharply reducing the number of paid compound claims and

PCCA sales. *See id.* ¶¶160–62, 172. TRICARE's denial of payment for almost all compound claims underscores the materiality of PCCA's fraudulent actions under *Escobar*.[14]

PCCA misreads the 2014 GAO report to claim that "the government stop[ped] paying claims and then start[ed] paying claims after it [knew] about the alleged misconduct." Dkt. 84 at 28. The report does not state that TRICARE stopped and then started paying compound claims. Instead, it reads, "[i]n June 2013, DOD informed beneficiaries that TRICARE would no longer pay for drugs dispensed by retail pharmacies that contain bulk drug substances. However, due to beneficiary complaints and enactment of new legislation concerning compounded drug safety and quality, DOD postponed this change." Dkt. 84-1 at 2–3. This passage does not suggest that TRICARE viewed the problem as minor or insubstantial. Nor does the GAO report state that TRICARE had actual knowledge of PCCA's fraud. As this court rightly observed, "[h]ealthcare administration is complicated. The Government does not enjoy the luxury of refusing to reimburse health care claims the moment it suspects there may be wrongdoing. . . . Thus, the Government's continued payment despite knowledge of Relator's allegations does not necessarily imply immateriality." *Montcrieff*, 507 F. Supp. 3d at 767 (quotations omitted).

PCCA erroneously claims "[t]he government concedes in its Complaint that it was aware by at least 2003 that AWPs were often 'manipulat[ed.]'" Dkt. 84 at 25. The complaint quotes OIG Guidance that expressly warned companies like PCCA against manipulating AWP. Dkt. 66

[14] The complaint specifically states that TRICARE denied payment "directly in response to the exorbitant reimbursements." Dkt. 66 ¶171. This allegation contradicts PCCA's contention that the complaint "fails to allege facts sufficient to allow the Court to conclude . . . TRICARE ever denied a single claim for payment based on the AWP of a compounded medication containing bulk substances." Dkt. 84 at 30. PCCA also states that "Exhibit 22 shows TRICARE reimbursed a pharmacy's April 2015 claim in September 2017." Dkt. 84 at 30. The payment of one claim in 2017 does not negate the fact that following the implementation of controls, TRICARE "refuse[d] to pay claims in the mine run of cases." *Escobar*, 579 U.S. at 195.

¶37. The guidance put PCCA on notice that its actions were illegal. It did not put the government on notice of PCCA's illegal actions, which occurred between 2012 and 2015.

PCCA argues (Dkt. 84 at 25) that AWPs represented a sticker price and that the government joined other lawsuits involving AWPs. These contentions do not show that the government had actual knowledge of PCCA's fraud alleged in this case. Further, the government's participation in other lawsuits alleging AWP fraud underscores its importance to the government. PCCA also mischaracterizes the complaint to argue that TRICARE had access to PCCA's spreads. Dkt. 84 at 32 (citing Dkt. 66 ¶45). The complaint does not allege that PCCA's customers submitted their acquisition costs or that TRICARE had access to them. Indeed, if PCCA's customers had submitted their actual acquisition costs in their compound claims, TRICARE would have paid based on the acquisition costs because they were far lower than the AWPs. Dkt. 66 ¶45. PCCA also urged its customers to hide their acquisition costs from payers like TRICARE. *Id.* ¶¶152–57.

PCCA asserts that "courts routinely dismiss claims when the government knows of the violation of certain requirements and continues to pay claims." Dkt. 84 at 24. Not only does PCCA wrongly place dispositive weight on a single *Escobar* factor, *see Harman*, 872 F.3d at 665 ("no single factor is outcome determinative"), but, as explained above, TRICARE acted quickly to stop payment after it had sufficient information. The cases cited by PCCA are inapplicable

because the government never stopped payment in those cases,[15] many were disposed of at summary judgment, and all involved facts vastly different than those alleged here.[16]

Claimed Significance of Express Scripts. PCCA contends that TRICARE "chose" ESI "(a company the government knew to have been accused of illegally profiting off of the fraudulent inflation of AWPs) to reimburse for non-covered compounded medications based on the AWP of the ingredients." Dkt. 84 at 2. PCCA fails to explain how this contention has any bearing on the materiality analysis. PCCA points to a separate *qui tam* case against ESI and others, which concerned neither PCCA nor the allegations at issue. *See United States v. Express Scripts, Inc.*,

[15] *See United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 35 (1st Cir. 2017) ("[T]here is no allegation that the FDA withdrew or even suspended product approval upon learning of" the alleged fraud.); *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016) (relator fell "short of pleading a causal link between the representations made to the FDA and the payments made by CMS"); *United States ex rel. Porter v. Magnolia Health Plan, Inc.*, 810 F. App'x 237, 242 (5th Cir. 2020) ("no specific allegations regarding the materiality of [defendant's fraud]" and Medicaid continued to pay); *United States ex rel. Patel v. Catholic Health Initiatives*, 792 F. App'x 296, 301 (5th Cir. 2019) ("Nothing in Relators' filings suggest[ed] that the government would stop the flow of funds[.]" (quotations omitted)); *United States ex rel. Kolchinsky v. Moody's Corp.*, 238 F. Supp. 3d 550, 555 (S.D.N.Y. 2017), *on reconsideration in part*, No. 12cv1399, 2017 WL 3841866 (S.D.N.Y. Sept. 1, 2017) (government "continued to pay").

[16] *See United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1030, 1033 (D.C. Cir. 2017) (summary judgment where "headcount data (false or not) had no bearing on costs"); *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 328–29 (9th Cir. 2017) (contractor complied with the statements of work, and the government accepted the work and paid); *United States ex rel. Thomas v. Black & Veatch Special Projects Corp.*, 820 F.3d 1162, 1172 (10th Cir. 2016) (relators offered "no evidence to demonstrate that the alteration of documents may have influenced [the government] not to pay" and the government never took action); *United States ex rel. Marshall v. Woodward, Inc.*, 812 F.3d 556, 563 (7th Cir. 2015) ("The government learned of plaintiffs' concerns, thoroughly investigated them, and determined that they were meritless."); *United States ex rel. Berg v. Honeywell Int'l, Inc.*, 740 F. App'x 535, 538 (9th Cir. 2018) (Army continued paying for several years "despite being aware of Relators' fraud allegations since 2002, the results of its own audit since 2003, and the problems with the infiltration rates since 2004"); *United States ex rel. Hartpence v. Kinetic Concepts, Inc.*, No. 208CV01885CASAGR, 2019 WL 3291582, at *12–16 (C.D. Cal. June 14, 2019) (no evidence government would not have paid had it known of noncompliance).

602 F. App'x 880, 881 (3d Cir. 2015) (involving "allegations that various pharmaceutical industry defendants profited from artificially inflated" AWPs "for brand-name drugs").

PCCA improperly asks the court to consider facts beyond the complaint (based on allegations in another lawsuit) and make inferences in favor of the defendant. PCCA also misstates the holding of that case, which affirmed dismissal of the relator's claims based on the FCA's public disclosure bar because the relator's allegations were based on information in the news media. *Id.* at 882–83. This suggests nothing about TRICARE's actual knowledge of PCCA's violations in this case.

PCCA claims, "[i]t is further notable that the Department of Justice, which is not subject to the public disclosure bar, chose not to intervene in the case." Dkt. 84 at 28. But there is nothing "notable" about the government's decision not to intervene in a particular case, and that decision "has no probative value and is not relevant." *United States ex rel. El-Amin v. George Washington University*, 533 F. Supp. 2d 12, 21–22 (D.D.C. 2008). The government's decision to decline a different lawsuit against a different defendant involving different allegations is irrelevant.

C. The Government Adequately Pleaded Scienter.

"Knowledge need not be pled with particularity under Rule 9(b); it need only be pled plausibly pursuant to Rule 8." *Bollinger*, 775 F.3d at 260. "The plausibility standard does not give district courts license to look behind a complaint's allegations and independently assess the likelihood that the plaintiff will be able to prove them at trial." *Id.* (quotations and alteration marks omitted). It is improper to "draw[] inferences against the United States" or "focus[] on facts the United States did not plead, rather than the inferences that the pleaded facts support." *Id.* at 261–63. To plead knowledge, the government must allege the defendant either (1) had "actual knowledge of falsity, (2) acted with deliberate ignorance of the truth or falsity of the information

provided, or (3) acted with reckless disregard of the truth or falsity of the information provided." *Hodge*, 933 F.3d at 473 (quotations omitted).

In *Bollinger*, the district court ruled that the defendant had not acted with knowledge under the FCA by reporting certain figures to the Coast Guard because "the United States failed to allege that [the defendant] knew the correct . . . figure and therefore concealed the true calculation." 775 F.3d at 261. The Fifth Circuit reversed the district court, explaining "[t]he FCA does not require the United States to show that [defendant] knew the *correct* figure." *Id*. (emphasis in original). According to the Fifth Circuit, "[t]he FCA is satisfied if the plaintiff alleges the defendant either knew the [reported] figure was false or acted with reckless disregard of its truth or falsity." *Id*. The district court also erred by drawing inferences against the government and in favor of the defendant and by failing to consider "circumstantial evidence and general allegations of [the defendant's] knowledge and intent." *Id*.

i. The Complaint Plausibly Alleges PCCA Acted with Actual Knowledge, Deliberate Ignorance, or Reckless Disregard.

The complaint satisfies the requirements for pleading knowledge under Rule 8. *See supra* Factual Background (describing knowledge in detail). To summarize, the complaint alleges that PCCA knew that inflating AWPs was risky, yet inflated them anyways; knew its inflated AWPs were false, fictitious, and fraudulent and attempted to prevent payers from comparing them to its selling prices; knew that its AWPs resulted in excessive and fraudulent compound claims to third-party payers; knew its members billed and received payment from TRICARE based on its AWPs; knew that its profits were dependent on TRICARE's continued payment of compound claims; and actively lobbied against TRICARE's changes to its reimbursement policies. *See* Dkt. 66 ¶¶7, 16,

53–56, 59, 65–74, 118–21, 152–63. These allegations more than plausibly allege that PCCA acted with actual knowledge, deliberate ignorance, or reckless disregard under the FCA.[17]

ii. PCCA Misreads *Safeco*, Which Does Not Hold That an FCA Defendant May Defeat Knowledge Based Upon a Post Hoc Interpretation.

PCCA argues that the complaint fails to satisfy the standard for knowledge set forth in *Safeco*, 551 U.S. 47, a case involving the Fair Credit Reporting Act (FCRA), not the FCA. PCCA contends that under *Safeco*, it cannot act "knowingly" if it offers an objectively reasonable interpretation and no authoritative guidance warns it away from its interpretation. Dkt. 84 at 33, 35. PCCA states that it could have held "a completely, objectively reasonable interpretation" that its products were not subject to TRICARE reimbursement even if PCCA did not actually hold that position at the time. *Id*. at 36–38.

This argument is meritless because (1) PCCA's interpretation regarding TRICARE's coverage of its ingredients has no bearing on PCCA's knowledge regarding its fraudulent AWP pricing scheme; (2) PCCA did not base its actions on this post hoc interpretation; and (3) the interpretation is objectively unreasonable. Here, the government alleges a fraudulent AWP pricing scheme and that PCCA acted with actual knowledge, deliberate ignorance, or reckless disregard as to the truth or falsity of its AWPs. That knowledge is not negated merely because PCCA now claims that it "could have held" the interpretation that its products were not covered. That interpretation is irrelevant to PCCA's knowledge regarding its AWP pricing fraud. Moreover, the

[17] PCCA cites *United States ex rel. Taylor-Vick v. Smith,* 513 F.3d 228 (5th Cir. 2008). Dkt. 84 at 33. There, the Fifth Circuit affirmed summary judgment for the defendants because, in relevant part, the relator could not "point to a single instance in which Defendants submitted a false claim to Medicare, let alone an instance in which Defendants *knowingly* or *recklessly* submitted such a claim." *Smith*, 513 F.3d at 232 (emphasis in original). Here, at the pleading stage, the government detailed PCCA's fraudulent scheme and knowledge and identified 325 examples of fraudulent claims submitted to TRICARE.

government's allegations, which must be taken as true, dispute any suggestion that PCCA based its actions on this interpretation. The complaint alleges the opposite—that PCCA knew TRICARE covered compound claims containing its ingredients and inflated its AWPs to induce sales of its ingredients, which its customers billed to TRICARE. *See* Dkt. 66 ¶¶5, 55–59, 65, 74, 118, 152–63. Therefore, the court should infer that PCCA is asserting a post hoc interpretation that it did not actually hold at the time of its fraudulent actions. At a minimum, there is a factual dispute, which the Court cannot resolve at the pleading stage.

Courts after *Safeco* have repeatedly rejected efforts by FCA defendants to disclaim FCA knowledge based on a post hoc interpretation. *See United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1155 (11th Cir. 2017); *United States ex rel. Marsteller v. Tilton*, 556 F. Supp. 3d 1291, 1308–09 (N.D. Ala. 2021); *United States ex rel. Morsell v. Symantec Corp.*, 471 F. Supp. 3d 257, 305 (D.D.C. 2020); *see also Montcrieff*, 507 F. Supp. 3d at 770 ("For an interpretation to be reasonable, it must actually be held."). Nor does *Safeco* or any other case cited by PCCA hold that a defendant's post hoc interpretation precludes FCA knowledge as a matter of law.

In *Safeco*, the Supreme Court addressed whether "willful" violations of the FCRA's notice provisions reach "reckless FCRA violations." 551 U.S. at 69. The Court assumed that the defendant adopted a reasonable but erroneous interpretation of an ambiguous statute. *See id.* at 70 n.20. Concluding that willfulness encompasses "reckless" conduct, the Court then addressed whether the non-compliance at issue was "reckless" under the FCRA. *Id.* at 68–69. Because there was "no indication that Congress had something else in mind," the Court applied the common law usage of "reckless" and held that "a company subject to FCRA does not act in reckless disregard of it unless the action is not only a violation under a reasonable reading of the statute's terms, but shows that the company ran a risk of violating the law substantially greater than the risk associated

with a reading that was merely careless." *Id*. at 69.[18] Nothing in *Safeco* suggests that a post hoc interpretation defeats "reckless" or "knowing" conduct as a matter of law.

In *United States v. SuperValu Inc.*, 9 F.4th 455, 468 (7th Cir. 2021), a split panel of the Seventh Circuit applied *Safeco* to the FCA's knowledge standard but rejected the contention that "defendants could escape liability by making a 'barely plausible' post hoc argument about a statute's meaning, 'even though the defendant ignored repeated and correct warnings.'"[19]

iii. Under *Halo*, PCCA Cannot Insulate Itself from FCA Liability by Manufacturing a Post Hoc Interpretation that It Did Not Hold.

In *Halo*, 579 U.S. 93, the Supreme Court clarified *Safeco* to make it clear that a defendant could not avoid enhanced damages under the Patent Act by asserting an objectively reasonable defense that it did not hold at the time. *Id.* at 106. In that case, the Federal Circuit had applied a test derived from *Safeco* that precluded enhanced damages if a defendant could "muster a reasonable" defense regardless of whether he acted "on the basis of the defense or was even aware of it." *Id.* at 105. The Supreme Court rejected the test because it allows "someone who plunders

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[18] *Safeco* applies, if at all, only to "reckless" conduct under the FCA, not to situations when a defendant (like PCCA) acts with "actual knowledge" or "deliberate ignorance" of falsity. The FCA has a different purpose and statutory language than the FCRA. By defining "knowledge" in separate and independent ways, Congress intended to impose FCA liability on a broad spectrum of "knowing" and "reckless" conduct. *See* S. Rep. No. 99-345, at 20 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5285 (defining the standard "as making liable those who have 'actual knowledge that the claim is false, fictitious, or fraudulent, or acts in gross negligence of the duty to make such inquiry as would be reasonable and prudent to conduct under the circumstances to ascertain the true and accurate basis of the claim'"). The Fifth Circuit has not yet addressed *Safeco*'s applicability to the FCA. It is not necessary for the Court to decide that question here.

[19] PCCA also cites another split decision, *United States ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340 (4th Cir. 2022). On May 10, 2022, however, the Fourth Circuit granted a petition for rehearing en banc, which automatically vacates the panel decision. No. 20-2330, 2022 WL 1467710 (4th Cir. May 10, 2022). Other circuit cases apparently did not involve post hoc interpretations. *See United States ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC*, 833 F.3d 874, 879–80 (8th Cir. 2016); *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 288–90 (D.C. Cir. 2015); *United States ex rel. McGrath v. Microsemi Corp.*, 690 F. App'x 551, 552 (9th Cir. 2017).

a patent—infringing it without any reason to suppose his conduct is arguably defensible—" to "escape any comeuppance under [the Patent Act] solely on the strength on his attorney's ingenuity." *Id*. The Court reasoned that "culpability is generally measured against the knowledge of the actor at the time of the challenged conduct." *Id.* The Court emphasized, "[n]othing in *Safeco* suggests that we look to facts that the defendant neither knew nor had reason to know at the time he acted." *Id.* at 106.[20]

Under *Halo,* a patent infringer cannot plunder a patent and then avoid enhanced damages under the Patent Act by asserting a post hoc "reasonable defense." *Id.* at 94. Similarly, an FCA defendant like PCCA cannot plunder (or cause the plunder of) the Treasury and escape accountability under the FCA by manufacturing a post hoc interpretation.

iv. PCCA's Post Hoc Interpretations Are Objectively Unreasonable.

1. PCCA's Post Hoc Interpretation that Its Ingredients Were Not Covered Is Objectively Unreasonable.

PCCA knew its customers billed TRICARE for PCCA ingredients at its inflated AWPs; profited and enriched itself from TRICARE's payment for its ingredients; caused TRICARE to pay hundreds of millions of dollars in inflated reimbursements; and took affirmative steps to delay changes to TRICARE's coverage and payment policies. *See* Dkt. 66 ¶¶1–16, 158–59. It is objectively unreasonable for PCCA now to argue that its ingredients were not covered and TRICARE should not have paid for them. *See United States ex rel. Drummond v. BestCare Lab.*

[20] The Court also rejected the defendant's argument that "bad faith" was irrelevant because "bad-faith infringement" is an independent basis for enhanced damages. *Halo*, 579 U.S. at 106 n.*. The FCA likewise defines "knowledge" to include "actual knowledge," which encompasses situations when a person acts with subjective awareness or in bad faith. *See Unicolors, Inc. v. H&M Hennes & Mauritz, L.P.*, 142 S. Ct. 941, 946–47 (2022) (ordinary meaning of "knowledge" is "actual, subjective awareness of both facts and the law"). Contrary to PCCA's contentions (Dkt. 84 at 36), its subjective awareness and bad faith are relevant to knowledge.

Servs., LLC, 950 F.3d 277, 281 (5th Cir. 2020) (rejecting defendants' "good-faith" reliance on a CMS manual "because there is no plausible reading of the CMS manual that could support the defendants' billing practices").[21]

As discussed above, neither the FCA nor the AKS is limited to fraudulent or kickback schemes for items that are "covered" or "reimbursable." PCCA has not cited a single case holding otherwise. In fact, a claim submitted to the government for items that are not covered or eligible for payment is itself a false claim under the FCA and thus satisfies the falsity element. *See Peterson*, 508 F.2d at 52 ("[T]he services billed were plainly not 'covered' and the Government thus paid on the basis of the false claims presented."); *United States ex rel. McNutt v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1260 (11th Cir. 2005) (government adequately alleged FCA and AKS violations where defendant submitted claims "knowing that they were ineligible for the payments demanded in those claims").

2. PCCA's Interpretation that It Could Inflate Its AWPs by 56,000 Percent Is Objectively Unreasonable.

Under PCCA's interpretation, it could inflate its AWPs by any amount without limitation and use the spreads generated by its markups to drive ingredient sales. *See* Dkt. 84 at 38. This interpretation is objectively unreasonable. Courts have consistently rejected such arguments, as explained above. And PCCA's interpretation leads to absurd outcomes, namely that AWPs marked up by 100,000% or even 1,000,000% cannot be false or fraudulent, and nothing would

[21] The attempt to blame TRICARE and ESI also amounts to an impermissible attempt to estop the government from enforcing the law based on the supposed actions of its agents. *See Heckler v. Cmty. Health Servs. of Crawford Cty., Inc.*, 467 U.S. 51, 53, 65–66 (1984) (holding that a Medicare provider could not stop the government from seeking a return of Medicare funds even though the provider relied on advice of the government's agent).

prohibit PCCA from marketing the resulting spreads with impunity. PCCA cites no caselaw to support that interpretation because none exists.[22]

PCCA contends the government fails "in not pleading a standard by which AWP can be measured or defined." Dkt. 84 at 38. But as explained, this is unnecessary. *See Zydus*, 2017 WL 1503986, at *11 (rejecting argument that relators cannot allege AWPs were false because there is no statute, regulation, rule, or contract defining AWP). And "[t]he FCA does not require the United States to show that [defendant] knew the *correct* figure." *Bollinger*, 775 F.3d at 261 (emphasis in original). "The FCA is satisfied if the plaintiff alleges [PCCA] either knew that [its AWPs were] false or acted with reckless disregard of [their] truth or falsity." *Id.* The government more than plausibly alleges that here.

PCCA cites (Dkt. 84 at 34–35) a statement in a concurring opinion from the Fifth Circuit, stating that "[w]here there are legitimate grounds for disagreement over the scope of a contractual or regulatory provision, and the claimant's actions are in good faith, the claimant cannot be said to have knowingly presented a false claim." *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 684 (5th Cir. 2003) (Jones, J., specially concurring). Here, PCCA's "grounds" for disagreement are objectively unreasonable, and the allegations in the complaint dispute any suggestion that PCCA's "actions [were] in good faith."

Moreover, the concurrence in *Southland Management* made this statement while discussing the government knowledge defense. *Id.* at 682. Under that defense, if the "government and a contractor have been working together" to "reach a common solution to a problem" and

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[22] PCCA cites *Purcell*, where the D.C. Circuit held the defendant's interpretation of an ambiguous term to be objectively reasonable and there was insufficient guidance that might have warned the defendant away from the view it took. 807 F.3d at 289. In this case, PCCA's interpretations are objectively unreasonable, and multiple court decisions (including from the First Circuit) and OIG Guidance should have warned PCCA away from its unreasonable interpretations.

"[i]f the government knows and approves of the particulars of a claim for payment before that claim is presented, the presenter cannot be said to have knowingly presented a fraudulent or false claim." *Id.* (quotations omitted). This defense is inapplicable because PCCA exploited TRICARE, sought to conceal information from it, prolonged its fraudulent scheme, and never presented the "particulars" of the claims before the claims were presented. Furthermore, "[t]he government knowledge defense is not appropriate at the motion to dismiss stage." *Bollinger*, 775 F.3d at 263.[23]

PCCA asserts that "the Court can infer one compelling[] and objectively reasonable basis by which to measure AWP from the government's allegations—PCCA's competitors." Dkt. 84 at 39. The competitor whose AWPs PCCA emulated in March 2012 settled with the government to resolve claims that it engaged in the same kind of fraudulent AWP scheme alleged here. *See* Dkt. 66 ¶174. PCCA cannot take refuge in its competitor's alleged fraud to justify its own misconduct.

v. Authoritative Guidance Warned PCCA Against Its Interpretations.

As cited above, many courts have found manufacturers liable for AWP fraud with markups far lower than those at issue here. In addition, the OIG Guidance specifically warned manufacturers against AWP manipulation, explaining that "it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the 'spread' to induce customers to purchase its product." Dkt. 66 ¶37 (quoting 68 Fed. Reg. at 23737). PCCA should have been warned away from its fraudulent AWP scheme.

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[23] PCCA's reliance on other cases (Dkt. 84 at 43–44) is similarly misplaced. *See United States v. Caremark, Inc.*, 634 F.3d 808, 818 (5th Cir. 2011) (district court's opinion "merely held" that factually true statements "cannot constitute a false statement for purposes of the FCA"); *United States ex rel. Parikh v. Citizens Med. Ctr.*, 977 F. Supp. 2d 654, 684 (S.D. Tex. 2013), *aff'd sub nom. Parikh v. Brown*, 587 F. App'x. 123 (5th Cir. 2014) (discussing scienter in holding that FCA did not provide a qualified immunity defense).

PCCA erroneously insists in a footnote that the OIG Guidance is inapplicable because it does not interpret AWP, was intended to apply to pharmaceutical manufacturers (not pharmaceutical suppliers), and relates to Medicare and Medicaid, not TRICARE. Dkt. 84 at 43 n.15. The warnings against AWP manipulation and marketing the spread do not depend on any definition of AWP. Rather, the warnings reflect the understanding that AWP manipulation "transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government)." 68 Fed. Reg. at 23737. The OIG Guidance is not limited to Medicare and Medicaid, but rather applies to all "Federal health care programs" including TRICARE and also applies to "manufacturers of other products that may be reimbursed by federal health care programs." *Id.* at 23742 nn.1, 5.

The specificity and detail of the OIG Guidance is precisely the type of guidance that "might have warned [PCCA] away from the view it took." *Safeco*, 551 U.S. at 70. The guidance should have raised red flags and alarm bells within PCCA that its egregious AWP manipulation and marketing of the spread were highly suspect. As the Seventh Circuit noted in *SuperValu*, the *Safeco* test "does not shield bad faith defendants that turn a blind eye to guidance indicating that their practices are likely wrong." 9 F.4th at 468.[24]

Additionally, the 2014 GAO report made clear what PCCA itself already knew—that TRICARE, in practice, paid for compound drugs with bulk ingredients like PCCA's. Thus, the report should have warned PCCA away from any belief it now claims it "could have" held that TRICARE did not reimburse for bulk ingredients. *See* Dkt. 84 at 36.

[24] Whether PCCA was "warned away" is also a "factual question." *See United States v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1052 (C.D. Cal. 2016). At a minimum, it would be inappropriate to decide such a question at the pleading stage, especially when there are significant questions as to whether PCCA held the claimed interpretation.

D. The Government Adequately Pleaded Causation.

The FCA reaches anyone who "knowingly assist[s] in causing" the government to pay claims grounded in fraud, "without regard to whether that person ha[s] direct contractual relations with the government." *Riley*, 355 F.3d at 378 (quotations omitted). The government need only allege that its losses were proximately caused by the defendant's unlawful conduct. *See Hodge*, 933 F.3d at 475. "A defendant's conduct may be found to have caused the submission of a claim for . . . reimbursement if the conduct was (1) a substantial factor in inducing providers to submit claims for reimbursement, and (2) if the submission of claims for reimbursement was reasonably foreseeable or anticipated as a natural consequence of defendants' conduct." *United States ex rel. Ruckh v. Salus Rehab.*, 963 F.3d 1089, 1107 (11th Cir. 2020) (quotations omitted).[25]

i. The Complaint Alleges PCCA's Actions Were a Substantial Factor in Causing the Submission of Inflated TRICARE Claims.

As described in detail in the Factual Background, the complaint plausibly alleges that PCCA's actions were (1) a substantial factor in causing customers to submit inflated claims to TRICARE; and (2) the submission of claims to TRICARE was reasonably foreseeable or anticipated as the natural consequence of PCCA's actions. *See* Dkt. 66 ¶¶150–51. The complaint provides extensive detail about PCCA's fraudulent AWP scheme (*id.* ¶¶52–64) and use of high AWPs and AWP spreads to drive sales of its ingredients (*id.* ¶¶73–111). The complaint also describes PCCA's efforts to assist its customers in maximizing profitability from its AWPs through training, billing software, consulting services, and educational seminars on third-party billing and

[25] Further, parties to a kickback arrangement are liable for causing the submission of claims that were a foreseeable consequence of the arrangement. *E.g.*, *United States ex rel. Freedman v. Suarez-Hoyos*, No. 8:04–cv–933–T–24 EAJ, 2012 WL 4344199, at *8 (M.D. Fla. Sept. 21, 2012); *see United States ex rel. Greenfield v. Medco*, 880 F.3d 89, 97 (3d Cir. 2018) (neither the AKS nor the FCA requires showing "that a kickback directly influenced a . . . decision to use a particular" provider).

"custom pricing strategies." *See id.* ¶¶112–17. PCCA's efforts were highly successful and fueled a rapid increase in the submission of compound prescription claims to TRICARE containing PCCA ingredients with inflated AWPs. *See id.* ¶¶133–34, 139–40.

ii. PCCA's Attempt to Blame TRICARE, ESI, and Its Customers Does Not Break the Chain of Causation and They Are Not Superseding Causes.

PCCA attempts to divert attention away from its role by casting blame on TRICARE—the victim of its fraudulent AWP scheme—and on other third parties, including ESI, third-party prescribers, and even its own customers. Dkt. 84 at 47. PCCA claims that TRICARE's loss was inevitable and entirely attributable to its own conduct. *See id.* According to PCCA, it had to follow the lead of its competitors or "potentially" go out of business. *See id.*

PCCA's effort to deflect blame does not break the direct chain of causation. As noted by the Supreme Court in an analogous context, "it is axiomatic under tort law that the exercise of judgment by the decision maker does not prevent the earlier agent's action . . . from being the proximate cause of the harm." *Staub v. Procter Hosp.*, 562 U.S. 411, 419 (2011). "The decisionmaker's exercise of judgment is *also* a proximate cause . . . but it is common for injuries to have multiple proximate causes." *Id.* (emphasis in original; citation omitted). "A cause can be thought superseding only if it is a cause of independent origin that was not foreseeable." *Id.* (quotations omitted).

PCCA fails to explain how actions of TRICARE, in paying for compound claims containing PCCA ingredients, and ESI, in adjudicating those compound claims for payment, are "superseding" causes. Nor does PCCA explain how the actions of third-party prescribers or its customers break the chain of causation or negate PCCA's direct and substantial role in causing the submission of inflated compound claims based on its AWPs. *See In re AWP Litig.*, 478 F. Supp. 2d at 175.

PCCA contends it had no choice but to inflate its AWPs because of TRICARE's use of AWP as a reimbursement metric and offers other excuses for its actions. Dkt. 84 at 47–49. Notably, these excuses are inconsistent with PCCA's position that it could not have known its customers were submitting claims to TRICARE and "could have held" the interpretation that its products were not covered or reimbursable by TRICARE. *Id*. at 36–38. They are a tacit admission that it knew its customers were submitting fraudulently inflated claims to TRICARE; that it knowingly assisted them in exploiting "an otherwise undefined regulatory scheme" (*id.* at 50); and that it took its actions to induce sales of its ingredients.

In any event, these excuses provide no legal cover for PCCA's fraudulent actions. Courts have repeatedly held that a defendant may not blame the victim or contend that the victim acted negligently as a defense to fraud. *See Blair*, 2021 WL 5040334, at *36; *United States v. Nekritin*, No. 10-CR-491 (S-2) (KAM), 2011 WL 2462744, at *7 (E.D.N.Y. June 17, 2011); *United States v. Letourneau*, No. 11 CR 182, 2013 WL 3834410, at *3 (N.D. Ill. July 24, 2013). The Court should reject PCCA's attempt to blame TRICARE and others for its own misconduct.

III. The Government Adequately Pleaded Common Law Claims.

A. The Government Was Not Required to Explicitly Plead in the Alternative.

PCCA contends that the Court must dismiss the federal common law claims because the complaint "fails to explicitly allege that its common law theories are pleaded in the alternative, and the claims incorporate by reference the allegations in the FCA claims." Dkt. 84 at 55. "[I]t is common for FCA plaintiffs to pursue related common law claims . . . based on the same set of facts." *Medoc*, 470 F. Supp. 3d at 659. "No technical form is required" in pleadings. Fed. R. Civ. P. 8(d)(1). A "party may state as many separate claims or defenses as it has, regardless of consistency," and "[p]leadings must be construed so as to do justice." Fed. R. Civ. P. 8(d)(3), (e). Courts do "not require hypertechnicality in pleading . . . claims in the alternative, and will not

dismiss" a claim "based on [a] failure to use more precise wording. . . . The claims need not be specifically pled in the alternative." *SIM Surgical, LLC v. Spinefrontier, LLC*, No. 4:20-cv-1060-JAR, 2020 WL 6822573, at *3 (E.D. Mo. Nov. 20, 2020).

Although the common law claims need not be pled in the alternative, it can be reasonably inferred that they are. The complaint lists the claims in separate causes of action, each of which incorporates the preceding allegations of the complaint. This pleading satisfies Rule 8. PCCA's reliance on *United States ex rel. Reeves v. Mercer Transportation Co.*, 253 F. Supp. 3d 1242 (M.D. Ga. 2017), is misplaced. Dkt. 84 at 55. That court dismissed claims for unjust enrichment and payment by mistake because there was an underlying contract—not an issue here. *Reeves*, 253 F. Supp. 3d at 1255–56. The court refused to dismiss other common law claims. *Id.*

B. The Government Adequately Pleaded a Payment by Mistake Claim.

Under payment by mistake, the government "can recover funds which its agents have wrongfully, erroneously, or illegally paid." *United States v. Wurts*, 303 U.S. 414, 415 (1938). To prevail, the government must show that it made payments under an erroneous belief, which was material to the payment decision. *United States ex rel. Roberts v. Aging Care Home Health, Inc.*, 474 F. Supp. 2d 810, 819 (W.D. La. 2007). Importantly, the government "is entitled to obtain repayment from a third party into whose hands the mistaken payments flowed where that party participated in and benefitted from the tainted transactions." *LTV Educ. Sys., Inc. v. Bell*, 862 F.2d 1168, 1175 (5th Cir. 1989). "The order in which the funds flowed is immaterial." *Id.*

The Government alleged that TRICARE paid claims "under the erroneous belief that the claims complied with the AKS" and were not being reimbursed at fraudulently inflated amounts. *United States ex rel. Capshaw v. White*, No. 3:12-CV-4457-N, 2018 WL 6523322, at *2 (N.D. Tex. Dec. 11, 2018). The complaint alleges that PCCA both caused and benefitted from those payments by reporting fraudulently inflated AWPs and marketing the resulting spreads to drive

sales of its ingredients. Dkt. 66 at ¶1. As a result, its customers billed and received reimbursement from TRICARE for compound drugs containing PCCA ingredients based on the inflated AWPs. *Id.* ¶¶1, 4. The reimbursement for these compound claims "depended heavily on [PCCA's] actions and directly benefitted [PCCA]." *See LTV*, 862 F.2d at 1175; *see also* Dkt. 66 ¶192.

PCCA cites *United States ex rel. Ramadoss v. Caremark Inc.*, No. SA-99-CA-00914-WRF, 2008 WL 3978101 (W.D. Tex. Aug. 27, 2008), for the proposition that the government cannot plead payment by mistake because payment did not flow "directly" to PCCA. Dkt. 84 at 56. In *Caremark*, the court granted summary judgment on Texas' payment by mistake claim, reasoning that Caremark did not receive "payments made by Texas Medicaid—either directly or indirectly" and there was no evidence Caremark benefitted from the alleged overpayments. 2008 WL 3978101, at *11. Not only was *Caremark* a summary judgment decision, but the complaint here alleges that PCCA benefitted from TRICARE's reimbursement through explosive growth in PCCA's sales to its customers, profits, and dividends. *See* Dkt. 66 ¶¶158–63. PCCA also contends a payment by mistake claim requires a contractual relationship. *See* Dkt. 84 at 57 n.18. The opposite is true. *See KIC*, 2019 WL 6884485, at *17 ("So-called quasi-contract theories such as payment by mistake . . . are generally precluded by the existence of an express contract.").

C. The Government Adequately Pleaded an Unjust Enrichment Claim.

Unjust enrichment "allows a plaintiff to recover money dictated by the needs of justice and fairness." *Id.* (quotations omitted). Unjust enrichment applies "where the person sought to be charged is in possession of funds which in good conscience and justice should not be retained, but should be delivered to the rightful owner." *United States v. Medica-Rents Co.*, 285 F. Supp. 2d 742, 777 (N.D. Tex. 2003). "[R]ecovery under unjust enrichment is justified when one person obtains a benefit from another by fraud, duress, or the taking of an undue advantage." *United*

States v. Medica-Rents Co., 2008 WL 3876307, at *3 (5th Cir. Aug. 19, 2008) (alteration in original).

By its fraudulent conduct, PCCA substantially increased its sales and was unjustly enriched at the government's expense. *See* Dkt. 66 ¶¶158–63, 193–96. Indeed, once TRICARE implemented additional controls for compound claims, PCCA's sales decreased sharply. *See id.* ¶¶161–63. As alleged in the complaint (Dkt. 66 ¶¶193–96), equity, good conscience, justice, and fairness require that PCCA return its ill-gotten gains to the government. *See United States ex rel. Stepe v. RS Compounding LLC*, 325 F.R.D. 699, 710 (M.D. Fla. 2017). In addition, because the government alleges that it paid the claims "under the erroneous belief that the claims complied with the AKS" and were not fraudulently inflated, the government "adequately pleads unjust enrichment." *Capshaw*, 2018 WL 6523322, at *2.

PCCA contends, without authority, that "the government's unjust enrichment claim fails because any benefit was conferred upon the member pharmacies in the form of allegedly excessive reimbursement of compounded medications." Dkt. 84 at 57. But PCCA caused those excessive reimbursements by inflating its AWPs, which benefitted and enriched PCCA through increased sales, profits, and dividends. PCCA further maintains that "[t]he government's unjust enrichment claim should also be dismissed because its own unlawful conduct 'caused' its loss." *Id.* at 58. To support the argument, PCCA cites *United States v. Hamdan*, No. 19-60-WBV-KWR, 2020 WL 2615916, at *11 (E.D. La. May 22, 2020), where criminal defendants tried to assert unjust enrichment as a defense against tax evasion charges. The case, which also applies Louisiana law, is plainly inapplicable. Regardless, as discussed above, PCCA cannot avoid liability for its unlawful conduct by blaming the government.

D. The Government Adequately Pleaded a Fraud Claim.

To plead common law fraud, "the Government must plausibly show there was (1) a false representation (2) in reference to a material fact (3) made with knowledge of its falsity (4) and with the intent to deceive (5) with action taken in reliance upon the representation." *Capshaw*, 2018 WL 6523322, at *2 (quotations omitted). A fraud claim is similar to an FCA claim but includes "the elements of reliance and damages." *See Grubbs*, 565 F.3d at 189.

As explained above, the government adequately pleaded falsity, materiality, knowledge, and causation. As to reliance, the complaint alleges PCCA made material misrepresentations in reporting inflated AWPs, which TRICARE relied on in determining reimbursement. Dkt. 66 ¶¶1, 5, 187. As to damages, "TRICARE paid hundreds of millions of dollars in excess reimbursement for tens of thousands of false and fraudulent" claims with "PCCA ingredients submitted by PCCA's customers." *Id.* ¶179. Exhibit 22 identified 325 example claims. If PCCA had not inflated its AWPs, TRICARE would not have reimbursed its ingredients at the inflated amounts. *Id.* ¶164. "In other words, the Complaint alleges that [TRICARE] relied on the truth of the claims, and paid them as a result. Thus, the Government adequately alleges reliance and damages for purposes of the fraud claim." *Medoc*, 470 F. Supp. 3d at 660.

PCCA asserts the complaint does not adequately allege fraud because the government was aware of the fraud or at least "circumstances were sufficient" to put it on notice. Dkt. 84 at 59–60. As discussed, these arguments are unavailing. The cases cited by PCCA are plainly inapplicable—particularly at the pleading stage.[26]

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[26] *See A.B.C. Packard, Inc. v. Gen. Motors Corp.*, 275 F.2d 63, 67–69 (9th Cir. 1960) (issue after jury trial was whether under Washington law car manufacturer owed duty to its distributor to disclose distributorship termination policy where written agreement existed between parties); *Fields v. Mitch Crawford's Holiday Motors Co.*, 947 S.W.2d 818, 821 (Mo. Ct. App. 1997) ("jury

PCCA maintains that "[t]he government also fails to allege that PCCA made any representation whatsoever to the government." Dkt. 84 at 60. But the law does not focus on whether an alleged misrepresentation was directly transmitted to the plaintiff; rather, it focuses on whether the defendant had reason to expect the misrepresentation would reach the plaintiff and induce reliance. *See OurLink, LLC v. Goldberg*, No. 3:08-CV-0745-P, 2008 WL 11425698, at *2–3 (N.D. Tex. Dec. 3, 2008) (rejecting defendants' argument that misrepresentations were not made to the plaintiff because the "[c]omplaint clearly alleges that the [defendants] had reason to expect that [plaintiff] would rely on the alleged misrepresentations"). PCCA knew its misrepresentations about AWPs would be relied upon by the government. *See* Dkt. 66 ¶¶5, 55–56, 59, 74, 118, 152. The case cited by PCCA is not on point because, unlike here, there was no allegation of reliance. *See Nat'l Rifle Ass'n of Am. v. Ackerman McQueen, Inc.*, No. 3:19-CV-2074-G, 2021 WL 3618113, at *16 (N.D. Tex. Aug. 16, 2021).

CONCLUSION

For the foregoing reasons, the Court should deny PCCA's Motion to Dismiss the Government's Complaint in Partial Intervention.

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was not required to believe there was an intent to defraud" and "could have reasonably concluded" car dealer "did not intentionally defraud" buyers).

DATED: May 23, 2022

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CERTIFICATE OF SERVICE

I certify that, on May 23, 2022, I served the foregoing document via CM/ECF on all counsel of record registered to receive CM/ECF notifications.

/s/ John M. Deck
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